



**Investigation of a safety-engineered device to prevent
needlestick injury:
Why hasn't StatLock stuck? A Pilot Study**

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3 **Investigation of a safety-engineered device to prevent needlestick injury:**
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5 **Why hasn't StatLock stuck?**
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Article Summary

Article Focus

This article sought to define whether an alternative safety engineered device (SED) could help prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central venous catheters (CVC). To begin to answer these questions the study involved three phases:

1. A retrospective analysis of de-identified occupational health records from our tertiary care urban United States (US) hospital to clearly identify how many HCW had NSI while placing CVC.
2. Ninety-five residents who frequently place CVC during training were surveyed regarding their knowledge and experience with NSIs and SEDs.
3. A random sample of six residents participated in a focus group session discussing barriers to use of the SED.

Key Messages

- A readily available safety-engineered device does exist as an alternative to using three sharps to suture a CVC.
- Sixteen percent (21 of 131) of NSIs occurring in residents and fellows over a 4-year period (July 2007–July 2011) of a single institution occurred during securement of an invasive catheter.
- If safety and efficacy of the device can be proven, 5.25 healthcare worker NSIs per year could be avoided at our institution. This would translate into a direct cost savings of \$19,362 over the 4-year period.

Strength and Limitations

- A notable strength of this work is that it addresses the International Healthcare Worker Safety Center March 2012¹ call to action to address a lack of new progress in NSI rates.

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3 The study identifies a new area where significant progress may be made to reduce
4 sharps injuries worldwide.
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8 • A significant limitation is that the study is currently limited to a single US tertiary care
9 site.
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3 Keywords: needlestick injury; sharps injury; safety-engineered device; healthcare worker injury;
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5 central venous catheter
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10 11 12 **ABSTRACT**

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16 Objective: This article sought to define whether an alternative safety engineered device (SED)
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18 could help prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central
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20 venous catheters (CVC).
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23 Design: The study involved three phases: 1) A retrospective analysis of de-identified
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25 occupational health records from our tertiary care urban US hospital to clearly identify NSI risk
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27 and rates to HCW during invasive catheter placement; 2) Ninety-five residents were surveyed
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29 regarding their knowledge and experience with NSIs and SEDs. 3) A random sample of six
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31 residents participated in a focus group session discussing barriers to use of the SED.
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34 Setting: A single urban US tertiary care teaching hospital.
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37 Participants: A retrospective analysis of NSI to HCW in a tertiary care urban US hospital was
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39 conducted over a 4-year period (July 2007–July 2011). Ninety-five residents from specialties
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41 that often place CVC during training (surgery, surgical subspecialties, internal medicine,
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43 anesthesia and emergency medicine) were surveyed regarding their experience with NSIs and
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45 SEDs. A random sample of six residents participated in a focus group session discussing
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47 barriers to use of the SED.
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50 Results: 314 NSIs were identified via occupational health records. Sixteen percent (21 of 131) of
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52 NSIs occurring in residents and fellows occurred during securement of an invasive catheter
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54 such as a CVC. If an SED device had been used, these 5.25 NSIs/year could have been
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56 avoided. Each NSI occurring in an HCW incurred an estimated average direct cost of \$922.
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58 Thus, utilization of the SED could have saved \$19,362 over the 4-year period.
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3 Conclusion: SEDs are currently available and can be used as an alternative to sharps. If safety
4 and efficacy can be demonstrated, then implementation of such devices can significantly reduce
5 the number of NSIs.
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14 There is no additional data available
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18 INTRODUCTION

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22 Needlestick or sharps injuries (NSIs) among healthcare workers (HCWs) are a common and
23 potentially avoidable injury. An estimated 600,000 to 800,000 percutaneous injuries occur
24 annually among HCWs in the United States². As high as these estimates appear, the literature
25 indicates that sharps injuries are significantly underreported³⁻⁵. These injuries place HCWs at
26 risk for blood-borne infections and result in considerable psychological distress. In addition, the
27 healthcare system incurs substantial costs from the occupational health testing, prophylaxis,
28 and follow-up that must be implemented for each reported NSI.
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37 Safety-engineered devices (SEDs) are promising design innovations intended to prevent
38 hazards and accidents. In medicine, numerous engineering controls have been introduced to
39 decrease the incidence of NSIs among HCWs, including safety-winged steel needles, safety
40 intravenous catheter insertion needles, and many others.
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50 The StatLock device (Bard Access Systems, Salt Lake City, UT) (Figure 1) is an SED designed
51 to prevent NSIs during placement of central venous catheters (CVCs). The StatLock device has
52 been available in all adult triple-lumen CVC kits in our urban tertiary care US institution since
53 July 2009. Despite its availability, the StatLock is not widely used in clinical practice. The
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3 purpose of our study was to perform a needs analysis by retrospectively examining HCW data
4 from our institution to determine whether implementation of the SED would significantly reduce
5 NSIs. We sought to determine whether practitioners did incur NSIs during the securement
6 phase of the CVC procedure, and if this could have been prevented with the use of this SED.
7 We also sought to identify potential barriers to implementation of a new SED in the healthcare
8 environment. The SED device was readily available in the safety triple lumen catheter kits within
9 the institution yet not utilized within the institution.
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21 We hypothesized that a substantial number of NSIs occur during resident placement of CVCs,
22 which might be prevented by use of the StatLock device. However, barriers including staff
23 resistance and training time are likely to impede implementation of safety controls.
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31 **METHODS**

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33 Institutional review board approval was obtained and all NSI data were de-identified. The study
34 was conducted at Hahnemann University Hospital (HUH), an urban tertiary care hospital in the
35 United States. We analyzed retrospective data on all NSIs reported between July 2007 and July
36 2011 by HCWs in the adult-care ACGME resident training programs (except neurosurgery).
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38 Ninety-five residents from disciplines responsible for CVC placement at our institution were
39 identified and enrolled in a prospective longitudinal study: surgery, emergency medicine,
40 internal medicine, and anesthesia. All participants signed written consent to participate. A plan
41 for compensation was incorporated into the study design to maximize return for 12-month
42 follow-up. Demographic data for each of the residents were collected, including level of training,
43 department, age, sex, race, and handedness. The survey questions were designed to determine
44 residents' prior exposure to NSIs and to evaluate their prior knowledge of and experience with
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3 the StatLock device. Each resident was randomly assigned to either a simulation curriculum or
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5 to a standard curriculum educational program to familiarize them with the SED device
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7 application, and all agreed to return in 12 months for a repeat questionnaire. The endpoint for
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9 the longitudinal phase of the study was defined as a difference in NSIs between the groups.
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11 This portion of the study is still in progress. Finally, a focus group of six randomly selected
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13 residents was conducted to assess impressions of the device and potential barriers to its
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15 implementation.
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18 19 **Data analysis**

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21 De-identified data on all NSIs occurring at our institution were independently reviewed by three
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23 study investigators (SG, AB, CR). All reported NSIs were reviewed and characterized according
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25 to occupation of the HCW incurring the injury and according to circumstances regarding the
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27 injury. Frequency counts of NSIs were tabulated (Figures 2 and 3). Frequency counts of
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29 physician NSIs that occurred during a catheter placement such as a CVC, large bore single
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31 lumen catheter, dialysis catheter, or arterial catheter line were also reviewed by the same three
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33 investigators and compared for agreement in interpretation. Audio-recorded focus group text
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35 was transcribed and data were extracted describing both positive and negative observations
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37 regarding the StatLock device.
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45 **RESULTS**

46 47 **Retrospective institutional data analysis**

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49 Analysis of the retrospective NSI data revealed that physicians (residents, fellows, and
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51 attendings) accounted for 43% (136 of 314) of the total NSIs occurring between July 2007 and
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53 July 2011 (Figure 2). Resident NSIs accounted for 87% (118 of 13) of the total physician NSIs
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55 (118 residents, 13 fellows, and 5 attending physicians) occurring during this 4-year period.
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3 Thirty-one percent of the resident/fellow NSIs injuries (40 of 131) occurred during the placement
4 of CVC or catheter lines that require securement to patient skin. Fifty-three percent (21 of 40) of
5 the NSIs that occurred during these procedures occurred while the line was being secured to
6 the patient's skin with a suture needle. This accounted for 16% (21 of 131) of the total number
7 of resident/fellow NSIs over the 4-year period. It is possible that 13 additional NSIs occurred
8 during securement of these catheter lines, but unless our occupational health record specifically
9 documented that the NSI occurred while the worker was securing the line, those data were not
10 included. An additional six NSIs occurred with the larger-bore needle while the worker was
11 attempting to cannulate the vessel.
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26 **Cost analysis**

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28 Given the numbers of NSIs determined from retrospective analysis, we calculated that use of a
29 needleless device to secure the CVC could have prevented these 21 NSIs, each costing an
30 estimated \$922 (average NSI cost incurred at this institution). Costs associated with an NSI
31 include provider fees for initial and follow-up visits, blood draw and analysis costs, medication
32 costs, and administrative costs. Costs vary from case to case depending on the treatment plan,
33 medication costs, and length of follow-up. Eliminating all 21 NSIs that definitively occurred
34 during securement of the line would have translated into a direct cost savings of \$19,362. If the
35 possible additional 13 NSIs also occurred during the securement phase where three sharps are
36 included in the calculation (hollow-bore needle for repeat anesthesia, suture needle, and
37 scalpel), this would translate to a direct cost savings of \$31,348 over the 4-year period. These
38 cost estimates do not include the indirect cost of time lost from work and other indirect financial
39 and social costs.
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57 **Enrollment survey of residents enrolled into the longitudinal study**

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3 The prospective portion of the study surveyed 95 residents. Only 30% had previous knowledge
4 of the needleless SED that is supplied in all CVC safety kits at our institution. Only 19% had
5 ever had training regarding the use of any SED or used the device in clinical practice. Twenty-
6 five percent of responding residents (24 of 95) answered yes when asked the question, "Have
7 you ever had a needlestick injury associated with patient body fluid exposure?" In a follow-up
8 question, we asked, "Did you report the incident each time?" Twenty-one percent (5 of 24)
9 responded that they did not always report NSI. This finding is consistent with prior data
10 suggesting that HCW NSIs are underreported³⁻⁶. Forty-nine percent of residents surveyed
11 stated that they had had at least one near miss/ close call needlestick incident in the past 2
12 months (Figure 4).
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28 **Focus group data**

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30 Focus group discussions were conducted with six randomly selected study participants.
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32 Participants were interviewed by a study investigator (SG) individually and each session was
33 audio recorded with the permission of the participant. Focus group sessions lasted an average
34 of 30 minutes to discuss participant use of the StatLock device, their impressions of the SED,
35 and additional thoughts they had on the use of StatLock over traditional sutures when securing
36 central lines. Audio data were extracted and analyzed by two independent study investigators
37 (SG and AB). Focus group data are presented in Table 1.
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49 Responses varied across participants. One surgery resident noted that surgeons especially are
50 more familiar with suturing than with applying StatLock and may be able to secure a CVC faster
51 using sutures. The resident stated, "Time is of the essence. [I] don't want to wait for StatLock to
52 dry when sutures are faster, more efficient, more comfortable." Another resident who is also
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3 comfortable and adept at suturing lines mentioned that she would want more practice with
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5 applying the StatLock device before using it in a clinical setting.
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10 One emergency medicine resident described himself as “motivated to use StatLock after
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12 witnessing multiple coworkers experience fingersticks.” After using the StatLock device just one
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14 time, he found the placement of the StatLock device was quicker than suturing the CVC.
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19 Two of the six residents reported that they valued the StatLock device in certain situations when
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21 they were more likely to incur an NSI, such as when the patient is unpredictable or unwilling to
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23 lie still. One resident reported that in such cases it is “beneficial to use as few sharps as
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25 possible.”
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30 Half of the residents were hesitant to use StatLock in certain circumstances because they
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32 thought that the nurses and other practitioners lacked knowledge about the device. After
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34 securing a CVC using StatLock in the emergency department, one resident reported, “The
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36 admitting team was confused, did not know what the device was, and [was] concerned over
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38 whether StatLock would stay in place.”
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46 One resident pointed out that the StatLock device may be beneficial in certain populations of
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48 patients. “[StatLock would be] beneficial cosmetically when placing an upper neck line next to
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50 the face, especially for patients who form keloids.”
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55 Audio-recorded focus group text was transcribed and data were extracted and categorized as
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57 neutral, positive or negative observations regarding the StatLock device.
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DISCUSSION

In 2009 we developed a partnership with our institutional industrial hygienist to investigate opportunities to reduce NSIs among resident physicians in our institution. In the fiscal year between 2008 and 2009, nurse NSIs increased 10% and physician NSIs increased 70% at our institution. In 2009 at HUH, 46% of the total reported NSIs involved residents. A 2007 study of 699 surgical residents at 17 US medical centers found that by the 5th year of residency, 99% had had at least one NSI. Moreover, for 53% of respondents, the NSI had involved a high-risk patient with a history of HIV infection, hepatitis B or C virus infection, or injection drug use.² In 2009, our US-based urban hospital reported 27.6 injuries per 100 occupied beds, which is above the EPINet average of 20.1 for teaching hospitals⁷. These data were alarming and required immediate analysis for the potential for intervention.

In medicine, engineering controls that have been introduced to decrease the incidence of NSIs among HCWs include safety-winged steel needles, safety intravenous catheter insertion needles, polyester film-coated capillary tubes, safety-shielded phlebotomy needles, needleless blood transfer devices, safety peripherally inserted central catheter stylets, blood gas needle-holding devices, blunt-tip needles, and shielded hypodermic needles/syringes⁸. Current literature indicates that 29% to 35% of reported occupational NSIs could have been prevented if an SED had been used⁹. Although engineering controls may require capital investment, the cost savings resulting from improved safety may justify the expense. However, devices that depend on user activation generate benefit only when correctly used; thus HCWs must be educated in their use.

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3 The StatLock SED secures CVCs using a locking device attached to the skin using benzoin
4 adhesive instead of the traditional method of using sharps. Traditionally, after a CVC is placed
5 the patient may require additional local anesthesia in a site separate from the insertion site,
6 necessitating the use of a hollow-bore needle. A CVC is secured with the use of a straight
7 suture needle and the suture is cut with a scalpel. Therefore, using the SED minimizes the risk
8 of NSI during securement of CVC by eliminating three steps in which sharps are used. Despite
9 the easy availability of the StatLock device, few resident physicians are aware of it and fewer
10 still have used it in clinical practice. Only 30% in our study had previous knowledge of the
11 needleless SED that is supplied in all CVC safety kits at our institution. Only 19% had ever used
12 the device in clinical practice.
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28 Despite increased awareness of sharps injuries and some attempts at prevention, NSIs
29 continue to be a serious problem. Our study supported earlier research findings that among
30 HCWs, physicians have the highest risk of NSI^{2, 10}, and among physicians, residents have a
31 three times greater risk of blood and body fluids exposure than senior doctors¹¹.
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39 In our institution, physicians have been reluctant to use the StatLock device because they have
40 questions about efficacy and patient safety. Some express concern that the device might not
41 work as well as the traditional method of securing a CVC to patients' skin using sutures. Many
42 reports in the literature have been authored by individuals associated with the manufacturers,
43 raising the question of potential bias. The StatLock device is currently available in every triple-
44 lumen CVC kit in our institution. Therefore, the issue of use of the device does not rest on its
45 availability, but rather on physician awareness, training, and preference.
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3 Focus group discussions revealed that such factors have indeed presented barriers to
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5 implementation of the StatLock device. Residents expressed concern regarding time constraints
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7 and familiarity with device. Previous literature has documented similar barriers to
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9 implementation. Cost, personnel time, and resistance to change are several of the most
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11 commonly documented deterrents.^{6, 12-16} Surgeons and anesthesiologists have been
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13 recognized as the cohorts least likely to use safety devices designed to prevent NSIs,
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15 presumably because they are skilled at suturing.¹⁷ Reluctance may also stem from feelings of
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17 discomfort and questions of efficacy.¹⁷ Evidence-based reasoning is often absent from the
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19 foundation of implementation programs, exacerbating opposition to change.¹⁸ Perpetual access
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21 to conventional sharps also hinders implementation of safety devices.¹⁹
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27 Some institutions have recognized that simple logistics can prevent staff from using safety-
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29 engineered devices. Contractual purchasing agreements can render devices unavailable and
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31 certain devices may not be compatible with existing equipment^{6, 16}. The overabundance of SEDs
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33 on the market makes it difficult for institutions to choose¹⁵, yet most devices are not applicable
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35 for all situations and technology must become more advanced to meet the remaining
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37 demand.^{15,18}
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42 Lastly, HCWs are characterized as being desensitized to disease and consequently possessing
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44 a false sense of security regarding the effects of NSIs.¹⁷ When this complacency is coupled
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46 with a lack of multidisciplinary support, both “horizontally and vertically,” implementation of
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48 safety devices becomes extremely difficult.²⁰
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55 CONCLUSIONS

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3 The common incidence of needlestick injuries among healthcare workers clearly indicates a
4 need for further intervention. Engineering controls such as needleless securement devices are
5 currently available and can be used as an alternative to sharps. Retrospective analysis of
6 institutional records demonstrated that over a 4-year period (July 2007–July 2011), 16% of
7 resident/fellow NSIs (21 of 131) could have been avoided with the use of a safety-engineered
8 device such as the Statlock device to secure a CVC. If safety and efficacy of the device can be
9 demonstrated, then implementation of such devices may significantly reduce the number of
10 needlestick injuries among physicians. However, education alone will not be sufficient to
11 overcome barriers to implementation.
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28
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30 funding source had no involvement in the study design; collection, analysis or interpretation
31 data; writing of the report; nor the decision to submit the paper for publication.
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38 **Contributorship**

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40 Dr Griswold-Theodorson had access to and takes responsibility for the integrity of the data and the
41 accuracy of the data analysis. Dr Griswold-Theodorson: contributed to study conception and design,
42 data collection, analysis and interpretation of the data, drafting of the manuscript, and critical revision
43 of the article for important intellectual content.
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49 Ms Bonaroti: contributed to study design, data collection, data analysis and interpretation, reviewing
50 and editing of the manuscript, and critical revision of the article for important intellectual content.
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52

53 Mr Rieder: contributed to study design, data collection and analysis, review and editing of the
54 manuscript.
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3 Mr Erbayri: contributed to study design, data collection and analysis, review and editing of the
4 manuscript.
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8 Dr Parsons: contributed to study design, data collection, data analysis and interpretation, reviewing,
9 editing, and section writing of the manuscript.
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12 Dr Nocera: contributed to study design, data collection and data interpretation, reviewing, editing,
13 section writing of the manuscript and critical revision of the article for important intellectual content.
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16 Dr Hamilton: contributed to interpretation of the data, reviewing, and editing of the manuscript and
17 critical revision of the article for important intellectual content.
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24 25 **Data Sharing** 26

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28 There is no additional unpublished data.
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31 32 **Competing Interests** 33

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35 None
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3 Figure 1. Right infraclavicular subclavian triple-lumen catheter secured with StatLock needleless
4 device (Bard Access Systems, Salt Lake City, UT). The StatLock needleless device replaces
5 the need for suturing with a locking device secured with benzoin and tape.
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10 Figure 2. NSI injury at Hahnemann Hospital by occupation from four year period: July 1, 2007 to
11 June 30, 2011. MD includes residents, attendings, and fellows. Nurse: includes nurses, nurse
12 anesthesia, and nurse practitioners. Others include respiratory therapy, environmental services,
13 laboratory personnel and others not categorized above.
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19 Figure 3. Needlestick injuries while inserting CVC or other invasive catheter requiring sutures at
20 Hahnemann University Hospital for the 4-year period July 1, 2007 to June 30, 2011.
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24 Figure 4. Close calls involving needlestick injuries witnessed in the 2 months preceding survey
25 administration in July 2011.
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29 Table 1 Data extracted from six randomly selected focus group participants
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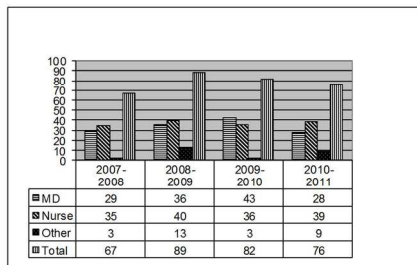


Figure 2. NSI injury at Hahnemann Hospital by occupation from four year period: July 1, 2007 to June 30, 2011. MD includes residents, attendings, and fellows. Nurse: includes nurses, nurse anesthesia, and nurse practitioners. Others include respiratory therapy, environmental services, laboratory personnel and others

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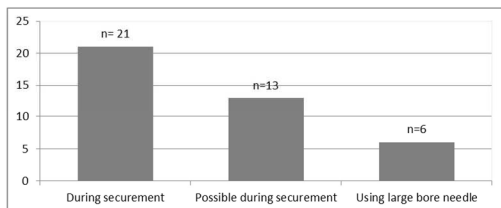


Figure 3. NSI injury while inserting CVC or other invasive catheter requiring sutures from four year period: July 1, 2007 to June 30, 2011. During securement was identified as a NSI during catheter securement; Possible during securement was not identified in the occupational health record whether with large bore needle or during securement with sharps. Using

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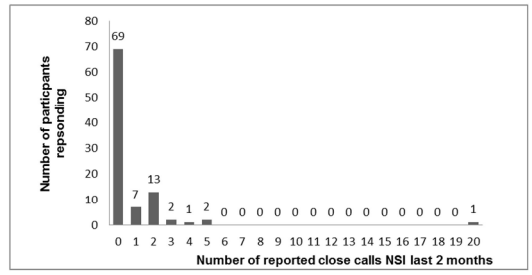


Figure 4. Close calls involving needlestick injuries witnessed in the 2 months preceding survey administration in July 2011.

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Table 1 Data extracted from six randomly selected focus group participants

Neutral comments	Positive comments	Negative comments
[I] would want more practice with applying the StatLock device before using it in a clinical setting.	“[I] am motivated to use StatLock after witnessing multiple coworkers experience fingersticks.”	“Time is of the essence. [I] don’t want to wait for StatLock to dry when sutures are faster, more efficient, more comfortable.”
	After using the StatLock device just one time, one resident found that the placement of the StatLock device was quicker than suturing the CVC.	Some residents were hesitant to use the device because the nurses and other practitioners lacked knowledge of the device.
	Two of the 6 residents reported that they valued the StatLock device in certain situations when they were more likely to incur an NSI. One stated this was particularly useful when the patient is unpredictable or unwilling to lie still.	“The admitting team was confused, did not know what device was, and [was] concerned over whether StatLock would stay in place.”
	One stated that the device	Resistance to StatLock due to

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	may be useful especially for patients who form keloids.	familiarity with suturing, especially among surgical residents
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**Investigation of a safety-engineered device to prevent
needlestick injury:
Why hasn't StatLock stuck?**

Journal:	<i>BMJ Open</i>
Manuscript ID:	bmjopen-2012-002327.R1
Article Type:	Research
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Primary Subject Heading:	Occupational and environmental medicine
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Keywords:	ACCIDENT & EMERGENCY MEDICINE, Health & safety < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, Risk management < HEALTH SERVICES ADMINISTRATION & MANAGEMENT, MEDICAL EDUCATION & TRAINING, Public health < INFECTIOUS DISEASES

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3 **Investigation of a safety-engineered device to prevent needlestick injury:**
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5 **Why hasn't StatLock stuck?**
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10 **Sharon Griswold¹, Alisha Bonaroti¹, Christopher J. Rieder², John Erbayri¹, Jessica**
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Article Summary

Article Focus

This article sought to determine whether an alternative safety engineered device (SED) could potentially prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central venous catheters (CVC). It also aims to identify potential reasons why an available SED is not utilized by HCW. To begin to answer these questions the study involved three phases:

1. A retrospective analysis of de-identified occupational health records from our tertiary care urban United States (US) hospital to clearly identify how many HCW had NSI while placing CVC.
2. Ninety-five residents who frequently place CVC during training were surveyed regarding their knowledge and experience with NSIs and SEDs.
3. A random sample of six residents participated in a focus group session discussing barriers to use of the SED.

Key Messages

- Sixteen percent (21 of 131) of NSIs occurring in residents and fellows over a 4-year period (July 2007–June 2011) in a single institution occurred during securement of an invasive catheter despite a readily available safety-engineered device that would eliminate the need for sharps during this part of invasive catheter insertion.
- If safety and efficacy of the device can be proven, 5.25 healthcare worker NSIs per year could be avoided at our institution. This would translate into a savings of at least \$57,183 in charges associated with NSIs over the 4-year period.
- Introduction of SED in an hospital should be accompanied by education, detailed information, and training of healthcare workers to encourage utilization of the device.

Strengths and Limitations

- A notable strength of this work is that it addresses the International Healthcare Worker Safety Center March 2012¹ call to action to address a lack of new progress in NSI rates. The study identifies a new area where significant progress may be made to reduce sharps injuries worldwide.
- A significant limitation is that the study is currently limited to a single US tertiary care site.

Keywords: needlestick injury; sharps injury; safety-engineered device; healthcare worker injury; central venous catheter

ABSTRACT

Objective: This article sought to define whether an alternative safety engineered device (SED) could help prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central venous catheters (CVC).

Design: The study involved three phases: 1) A retrospective analysis of de-identified occupational health records from our tertiary care urban US hospital to clearly identify NSI risk and rates to HCW during invasive catheter placement; 2) Ninety-five residents were surveyed regarding their knowledge and experience with NSIs and SEDs. 3) A random sample of six residents participated in a focus group session discussing barriers to use of the SED.

Setting: A single urban US tertiary care teaching hospital.

Participants: A retrospective analysis of NSI to HCW in a tertiary care urban US hospital was conducted over a 4-year period (July 2007–June 2011). Ninety-five residents from specialties that often place CVC during training (surgery, surgical subspecialties, internal medicine,

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3 anesthesia and emergency medicine) were surveyed regarding their experience with NSIs and
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5 SEDs. A random sample of six residents participated in a focus group session discussing
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7 barriers to use of the SED.
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10 Results: 314 NSIs were identified via occupational health records. Sixteen percent (21 of 131) of
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12 NSIs occurring in residents and fellows occurred during securement of an invasive catheter
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14 such as a CVC. If an SED device had been used, these 5.25 NSIs/year could have been
15
16 avoided. Each NSI occurring in an HCW incurred at least \$2,723 in charges. Thus, utilization of
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18 the SED could have saved a minimum of \$57,183 over the 4-year period.
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21 Conclusion: SEDs are currently available and can be used as an alternative to sharps. If safety
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23 and efficacy can be demonstrated, then implementation of such devices can significantly reduce
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25 the number of NSIs.
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29 There is no additional data available
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32 33 INTRODUCTION

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36 Needlestick or sharps injuries (NSIs) among healthcare workers (HCWs) are a common and
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38 potentially avoidable injury. An estimated 600,000 to 800,000 percutaneous injuries occur
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40 annually among HCWs in the United States². As high as these estimates appear, the literature
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42 indicates that sharps injuries are significantly underreported³⁻⁵. These injuries place HCWs at
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44 risk for blood-borne infections and result in considerable psychological distress. In addition, the
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46 healthcare system incurs substantial costs from the occupational health testing, prophylaxis,
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48 and follow-up that must be implemented for each reported NSI.
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54 Safety-engineered devices (SEDs) are promising design innovations intended to prevent
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56 hazards and accidents. In medicine, numerous engineering controls have been introduced to
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3 decrease the incidence of NSIs among HCWs, including safety-winged steel needles, safety
4 intravenous catheter insertion needles, and many others.
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11 The StatLock device (Bard Access Systems, Salt Lake City, UT) (Figure 1) is an SED designed
12 to prevent NSIs during placement of central venous catheters (CVCs). It is a locking device that
13 secures CVCs to the skin with benzoin adhesive instead of the traditional method of using
14 sutures to secure CVCs to skin. Traditionally, after a CVC is placed the patient may require
15 additional local anesthesia in a site separate from the insertion site, necessitating the use of a
16 hollow-bore needle for lidocaine injection. Then, a straight suture needle is used to suture the
17 CVC to the patient's skin. After making a knot with the suture, the ends are then cut with a
18 scalpel. Therefore, using the SED minimizes the risk of NSI during securement of CVC by
19 eliminating three steps during which sharps are used. Despite the easy availability of the
20 StatLock device, few resident physicians are aware of it and fewer still have used it in clinical
21 practice.
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38 This SED has been available in all adult triple-lumen CVC kits in our urban tertiary care US
39 institution since July 2009. Despite its availability, the SED is not widely used in clinical practice.
40 The purpose of our study was to perform a needs analysis by retrospectively examining HCW
41 data from our institution to determine whether implementation of the SED would significantly
42 reduce NSIs. We sought to determine whether practitioners did incur NSIs during the
43 securement phase of the CVC procedure, and if this could have been prevented with the use of
44 this SED. Since this SED device has already been readily available in the safety triple lumen
45 catheter kits within the institution, but not yet utilized on a regular basis, we also sought to
46 identify the potential barriers to implementation of a new SED in the healthcare environment.
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6 We hypothesized that a substantial number of NSIs occur during resident placement of CVCs
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8 and could potentially be prevented by use of the SED. However, barriers to the utilization of this
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10 SED, including lack of training on the use of the device and staff resistance are likely to impede
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12 implementation of safety controls.
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14 15 16 17 18 **METHODS**

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20 Institutional review board approval was obtained and all NSI data were de-identified. The study
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22 was conducted at Hahnemann University Hospital (HUH), an urban tertiary care hospital in the
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24 United States. We analyzed retrospective data on all NSIs reported between July 2007 and
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26 June 2011 by HCWs in the adult-care ACGME resident training programs (except
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28 neurosurgery).
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34 NSI cost was determined by adding the required charges for a “minimal risk” NSI. For the
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36 purpose of this study, a minimal risk NSI was defined as an NSI for which the HCW has a low
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38 risk for sero-conversion to Hepatitis or HIV viral infection. When this type of NSI occurs, both
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40 the HCW and source patient would be tested for HIV and Hepatitis B and C immediately after
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42 the NSI. The sum of the charges for the required occupational health appointments and initial
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44 lab tests represents the lowest possible cost of a NSI in USD. When the potential risk of
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46 transmission of Hepatitis or HIV infection is considered greater, the HCW may be prescribed
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48 prophylactic medications and requires repeat tested at regular intervals up to a year after a NSI,
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50 significantly increasing the costs associated with NSI.
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3 Ninety-five residents from surgery, emergency medicine, internal medicine, and anesthesia
4 programs, the disciplines responsible for CVC placement at our institution, were identified and
5 enrolled in the study. All participants signed written consent to participate. Demographic data for
6 each of the residents were collected, including level of training, department, age, sex, race, and
7 handedness. Survey questions were designed to determine residents' prior exposure to NSIs
8 and to evaluate their prior knowledge of and experience with the StatLock device.
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19 Finally, a focus group of six randomly selected residents was conducted to assess impressions
20 of the device and to identify potential barriers to its implementation. Participants were
21 interviewed by a study investigator (SG) individually and each session was audio recorded with
22 the permission of the participant. During the focus group sessions, participants were asked to
23 discuss their impressions of the SED, and additional thoughts they had on the use of this
24 alternative method as compared to traditional sutures when securing central lines. These
25 discussions were recorded so that they could be later analyzed by two independent study
26 investigators (SG and AB).
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40 **Data analysis**

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42 De-identified data on all NSIs occurring at our institution were independently reviewed by three
43 study investigators (SG, AB, CR). All reported NSIs were reviewed and characterized according
44 to occupation of the HCW incurring the injury (Figure 2) and according to circumstances
45 regarding the injury. Frequency counts of physician NSIs that occurred during a catheter
46 placement such as a CVC, large bore single lumen catheter, dialysis catheter, or arterial
47 catheter line were also reviewed by the same three investigators and compared for agreement
48 in interpretation. After the focus group sessions, two independent study investigators
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3 categorized the residents' statements as neutral, positive, or negative observations regarding
4 the StatLock device.
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10 **RESULTS**

11 **Retrospective institutional data analysis**

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13 Analysis of the retrospective NSI data revealed that physicians (residents, fellows, and
14 attendings) accounted for 43% (136 of 314) of the total NSIs occurring between July 2007 and
15 June 2011 (Figure 2). Resident NSIs accounted for 87% (118 of 136) of the total physician
16 NSIs occurring during this 4-year period. Analysis of the circumstances surrounding each NSI
17 showed that 40 NSIs occurred during the placement of CVCs or other catheter lines that
18 required securement to patient skin. Fifty-three percent (21 of 40) of the NSIs that occurred
19 during these procedures occurred specifically while the line was being secured to the patient's
20 skin with a suture needle. This accounted for 16% (21 of 131) of the total number of resident
21 and fellow NSIs over the 4-year period. It is possible that 13 additional NSIs occurred during
22 securement of these catheter lines, but unless our occupational health record specifically
23 documented that the NSI occurred while the worker was securing the line to the patient's skin,
24 those data were not included. The remaining six NSIs that occurred during placement of a CVC
25 or other invasive catheter occurred with the large-bore needle while the physician was
26 attempting to cannulate the vessel.
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49 **Cost analysis**

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51 Given the number of NSIs determined from retrospective analysis, we calculated that use of a
52 needleless device to secure the CVC could have prevented 21 NSIs. The cost analysis
53 estimates that each NSI incurs at least \$2,723 USD in charges at this institution. Table 1 lists
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3 the minimal charges associated with a low risk NSI using data from our institution's
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5 Occupational Health Clinic. While the calculations for this study represent the lowest possible
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7 cost of a NSI, the actual cost of a NSI varies from case to case depending on the circumstances
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9 surrounding the NSI, the treatment plan, medication requirements, and frequency of follow-up
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11 visits. If the HCW has a high risk exposure to HIV, prophylactic antiviral medications must be
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13 prescribed and the cost of the medications, additional labwork, and frequent follow-up visits
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15 increases the cost of the NSI significantly. The cost estimates also do not include the indirect
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17 cost of time lost from work and other indirect financial and social costs. Eliminating all 21 NSIs
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19 that definitively occurred during securement of a CVC would have translated into a savings of at
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21 least \$57,183 in USD charges.. If the additional 13 NSIs that possibly occurred during the
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23 securement phase were also prevented, the cost savings would be at least \$92,582 over the 4-
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25 year period.
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32 **Survey of residents**

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35 Of the 95 residents surveyed, only 30% had previous knowledge of the needleless SED that is
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37 supplied in all CVC safety kits at our institution. Only 19% had ever had training regarding the
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39 use of any SED or used the device in clinical practice. Twenty-seven percent of residents
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41 surveyed stated that they had had at least one close call needlestick incident in the past 2
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43 months. And 20% of the residents surveyed had at least two near miss/close call needlestick
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45 incident in the past 2 months. (Figure 4). Twenty-five percent of responding residents (24 of 95)
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47 answered yes when asked the question, "Have you ever had a needlestick injury associated
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49 with patient body fluid exposure?" In a follow-up question, we asked, "Did you report the incident
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51 each time?" Twenty-one percent (5 of 24) responded that they did not always report NSI. This
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53 finding is consistent with prior data suggesting that HCW NSIs are underreported³⁻⁶.
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Focus group data

Data from discussions with six randomly selected study participants are presented in Table 2. Statements regarding each residents' experience with Statlock were categorized into positive, negative, or neutral. Opinions of the SED and experiences varied across participants. In general, those residents who were comfortable and adept at suturing, especially surgical residents, seemed to prefer using sutures over the Statlock device. According to the responses, the use of the SED may also be dependent on patient characteristics, situational circumstances, and knowledge or acceptance of the SED by other HCWs. One resident indicated that she would want additional practice with the device before using it in a clinical setting, suggesting that additional training may encourage increased use of the SED.

DISCUSSION

In 2009 we developed a partnership with our institutional industrial hygienist to investigate opportunities to reduce NSIs among resident physicians in our institution. In the fiscal year between 2008 and 2009, nurse NSIs increased 10% and physician NSIs increased 70% at our institution. In 2009 at HUH, 46% of the total reported NSIs involved residents. A 2007 study of 699 surgical residents at 17 US medical centers found that by the 5th year of residency, 99% had had at least one NSI. Moreover, for 53% of respondents, the NSI had involved a high-risk patient with a history of HIV infection, hepatitis B or C virus infection, or injection drug use.² In 2009, our US-based urban hospital reported 27.6 injuries per 100 occupied beds, which is above the EPINet average of 20.1 for teaching hospitals⁷. Despite increased awareness of sharps injuries and some attempts at prevention, NSIs continue to be a serious problem. Our study supported earlier research findings that among HCWs, physicians have the highest risk of NSI^{2, 10}, and among physicians, residents have a three times greater risk of blood and body

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3 fluids exposure than senior doctors¹¹. These data were alarming and required immediate
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5 analysis for the potential for intervention.
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11 In medicine, engineering controls that have been introduced to decrease the incidence of NSIs
12 among HCWs include safety-winged steel needles, safety intravenous catheter insertion
13 needles, polyester film-coated capillary tubes, safety-shielded phlebotomy needles, needleless
14 blood transfer devices, safety peripherally inserted central catheter stylets, blood gas needle-
15 holding devices, blunt-tip needles, and shielded hypodermic needles/syringes⁸. Current
16 literature indicates that 29% to 35% of reported occupational NSIs could have been prevented if
17 an SED had been used⁹. Although engineering controls may require capital investment, the
18 cost savings resulting from improved safety may justify the expense. However, devices that
19 depend on user activation generate benefit only when correctly used; thus HCWs must be
20 educated in their use.
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35 For some HCW their lack of training and their unfamiliarity with SEDs is a major barrier to its
36 use. Only 30% in our study had previous knowledge of the needleless SED that is supplied in
37 all CVC safety kits at our institution. Only 19% had ever used the device in clinical practice.
38 Exposure to the SED and effective training may encourage the use of SEDs and subsequently
39 reduce NSI. A prospective cohort study using the same 95 residents who participated in this
40 survey has been designed to determine the best means of educating residents on the use of the
41 Statlock device. Each resident was randomly assigned to either a standard teaching video or a
42 simulation curriculum involving both the video teaching plus hands-on practice in a simulated
43 clinical environment. The endpoint for the longitudinal phase of the study was defined as a
44 difference in NSIs between the groups. Additionally, all participants agreed to return in 12
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3 months for a repeat questionnaire on their attitudes and experience with the SED. This portion
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5 of the study is still in progress.
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10 In our institution, some residents who are already familiar with Statlock have been reluctant to
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12 use it because they have questions about efficacy and patient safety. Some express concern
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14 that the device might not work as well as the traditional method of securing a CVC to patients'
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16 skin using sutures. Many reports in the literature have been authored by individuals associated
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18 with the manufacturers, raising the question of potential bias. The StatLock device is currently
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20 available in every triple-lumen CVC kit in our institution. Therefore, the issue of use of the
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22 device does not rest on its availability, but rather on physician awareness, training, and
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24 preference.
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29 Focus group discussions revealed that such factors have indeed presented barriers to
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31 implementation of the SED. Residents expressed concern regarding time constraints and
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33 familiarity with device. Previous literature has documented similar barriers to implementation.
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35 Cost, personnel time, and resistance to change are several of the most commonly documented
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37 deterrents.^{6, 12-16} Surgeons and anesthesiologists have been recognized as the cohorts least
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39 likely to use safety devices designed to prevent NSIs, presumably because they are skilled at
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41 suturing.¹⁷ Reluctance may also stem from feelings of discomfort and questions of efficacy.¹⁷
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43 Evidence-based reasoning is often absent from the foundation of implementation programs,
44
45 exacerbating opposition to change.¹⁸ Perpetual access to conventional sharps also hinders
46
47 implementation of safety devices.¹⁹
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53 Some institutions have recognized that simple logistics can prevent staff from using safety-
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55 engineered devices. Contractual purchasing agreements can render devices unavailable and
56
57 certain devices may not be compatible with existing equipment^{6, 16}. The overabundance of SEDs
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3 on the market makes it difficult for institutions to choose¹⁵, yet most devices are not applicable
4
5 for all situations and technology must become more advanced to meet the remaining
6
7 demand.^{15,18}
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11 Lastly, HCWs are characterized as being desensitized to disease and consequently possessing
12
13 a false sense of security regarding the effects of NSIs.¹⁷ When this complacency is coupled
14
15 with a lack of multidisciplinary support, both “horizontally and vertically,” implementation of
16
17 safety devices becomes extremely difficult.²⁰
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20 21 22 23 **CONCLUSIONS**

24
25 The common incidence of NSIs among healthcare workers clearly indicates a need for further
26
27 intervention. Retrospective analysis of institutional records demonstrated that over a 4-year
28
29 period (July 2007–June 2011), 16% of resident/fellow NSIs (21 of 131) could have been avoided
30
31 with the use of a needleless securement device such as the Statlock device. While such SEDs
32
33 are currently available, they are infrequently used by HCWs for various reasons. The
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35 implementation of an SED in an institution requires proof of safety and efficacy as well education
36
37 and training of healthcare workers to encourage the use of the device and reduce the number of
38
39 NSIs among physicians.
40
41

42 43 **Funding**

44
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46
47 funding source had no involvement in the study design; collection, analysis or interpretation
48
49 data; writing of the report; nor the decision to submit the paper for publication.
50
51

52 53 54 **Contributorship**

1
2
3 Dr Griswold-Theodorson had access to and takes responsibility for the integrity of the data and the
4 accuracy of the data analysis. Dr Griswold-Theodorson: contributed to study conception and design,
5 data collection, analysis and interpretation of the data, drafting of the manuscript, and critical revision
6 of the article for important intellectual content.
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10
11 Ms Bonaroti: contributed to study design, data collection, data analysis and interpretation, reviewing
12 and editing of the manuscript, and critical revision of the article for important intellectual content.
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15
16 Mr Rieder: contributed to study design, data collection and analysis, review and editing of the
17 manuscript.
18

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21 Mr Erbayri: contributed to study design, data collection and analysis, review and editing of the
22 manuscript.
23

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25
26 Dr Parsons: contributed to study design, data collection, data analysis and interpretation, reviewing,
27 editing, and section writing of the manuscript.
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31 Dr Nocera: contributed to study design, data collection and data interpretation, reviewing, editing,
32 section writing of the manuscript and critical revision of the article for important intellectual content.
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35
36 Dr Hamilton: contributed to interpretation of the data, reviewing, and editing of the manuscript and
37 critical revision of the article for important intellectual content.
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39 40 41 42 43 **Data Sharing**

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46 There is no additional unpublished data.
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48 49 50 **Competing Interests**

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54 None
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3 Figure 1. Right infraclavicular subclavian triple-lumen catheter secured with StatLock needleless
4 device (Bard Access Systems, Salt Lake City, UT). The StatLock needleless device replaces
5 the need for suturing with a locking device secured with benzoin and tape.
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10 Figure 2. NSI injury at Hahnemann Hospital by occupation from four year period: July 1, 2007 to
11 June 30, 2011. MD includes residents, attendings, and fellows. Nurse: includes nurses, nurse
12 anesthesia, and nurse practitioners. Others include respiratory therapy, environmental services,
13 laboratory personnel and others not categorized above.
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20 Figure 3. Close calls involving needlestick injuries witnessed in the 2 months preceding survey
21 administration in July 2011.
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24 Table 1. Minimal charges associated with a low risk needlestick injury at Hahnemann Hospital.
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27 Table 2. Data extracted from discussions with six randomly selected focus group participants.
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For peer review only

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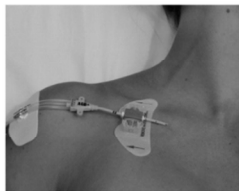


Figure 1. Right infraclavicular subclavian triple lumen catheter secured with SED needleless device. The device replaces the need for suturing with a locking device secured with benzoin

386x90mm (300 x 300 DPI)

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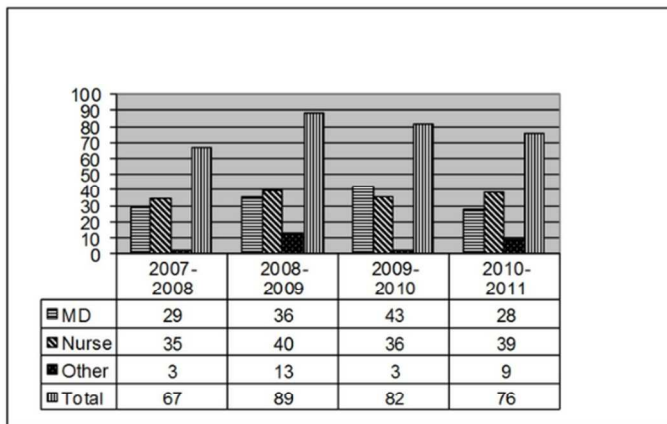


Figure 2. NSI injury at Hahnemann Hospital by occupation from four year period: July 1, 2007 to June 30, 2011. MD includes residents, attendings, and fellows. Nurse: includes nurses, nurse anesthesia, and nurse practitioners. Others include respiratory therapy, environmental services, laboratory personnel and others

145x90mm (300 x 300 DPI)

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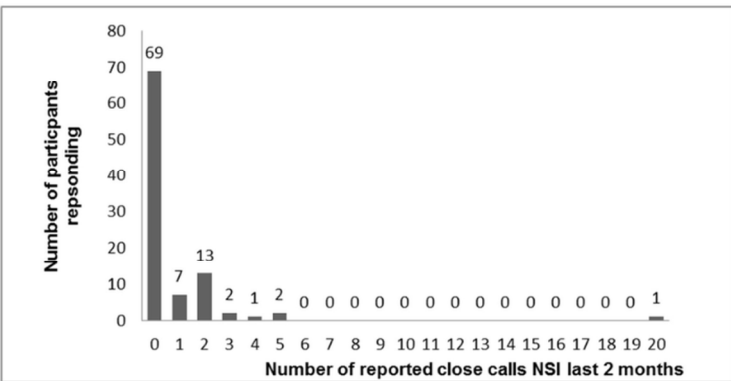


Figure 3. Close calls involving needlestick injuries witnessed in the 2 months preceding survey administration in July 2011.

200x90mm (300 x 300 DPI)

Peer review only

Table 1. Needlestick Injury Costs Per Incident Occupational Health Charges		
	2011 USD charges for “minimal risk” HCW exposure	Additional charges if more follow up visits deemed necessary
Office Visit (during weekday business hours)		
Initial visit	\$240	
Each additional follow up visit		\$76
Lab Costs		
HIV 1,2 Antibody Test		
Initial source patient	\$533	
HCW testing at baseline and each follow up interval		\$533
Hepatitis B Panel		
Initial source patient	\$511	
HCW testing at baseline and each follow up interval		\$511
Hepatitis C Panel		
Initial source patient	\$863	
HCW testing at baseline and each follow up interval		\$863
Total Cost	\$2732	Varies by Number of follow up visits required

Table 2. Data extracted from six randomly selected focus group participants

Neutral comments	Positive comments	Negative comments
[I] would want more practice with applying the StatLock device before using it in a clinical setting.	“[I] am motivated to use StatLock after witnessing multiple coworkers experience fingersticks.”	“Time is of the essence. [I] don’t want to wait for StatLock to dry when sutures are faster, more efficient, more comfortable.”
	After using the StatLock device just one time, one resident found that the placement of the StatLock device was quicker than suturing the CVC.	Some residents were hesitant to use the device because the nurses and other practitioners lacked knowledge of the device.
	Two of the 6 residents reported that they valued the StatLock device in certain situations when they were more likely to incur an NSI. One stated this was particularly useful when the patient is unpredictable or unwilling to lie still.	“The admitting team was confused, did not know what device was, and [was] concerned over whether StatLock would stay in place.”
	One stated that the device	Resistance to StatLock due

	may be useful especially for patients who form keloids.	to familiarity with suturing, especially among surgical residents
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For peer review only

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3 1 **Investigation of a safety-engineered device to prevent needlestick injury:**

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5 2 **Why hasn't StatLock stuck?**

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9 4 **Sharon Griswold¹, Alisha Bonaroti¹, Christopher J. Rieder², John Erbayri¹, Jessica**
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11 5 **Parsons¹, Romy Nocera¹, Richard Hamilton¹**

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Article Summary

Article Focus

This article sought to ~~define~~ determine whether an alternative safety engineered device (SED) could ~~potentially help~~ prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central venous catheters (CVC). It also aims to identify potential reasons why an available SED is not utilized by HCW. To begin to answer these questions the study involved three phases:

1. A retrospective analysis of de-identified occupational health records from our tertiary care urban United States (US) hospital to clearly identify how many HCW had NSI while placing CVC.
2. Ninety-five residents who frequently place CVC during training were surveyed regarding their knowledge and experience with NSIs and SEDs.
3. A random sample of six residents participated in a focus group session discussing barriers to use of the SED.

Key Messages

- ~~A readily available safety-engineered device does exist as an alternative to using three sharps to suture a CVC.~~
- Sixteen percent (21 of 131) of NSIs occurring in residents and fellows over a 4-year period (July 2007–June 2011) ~~in~~ a single institution occurred during securement of an invasive catheter despite a readily available safety-engineered device that would eliminate the need for sharps during this part of invasive catheter insertion.
- If safety and efficacy of the device can be proven, 5.25 healthcare worker NSIs per year could be avoided at our institution. This would translate into a ~~direct cost~~ savings of at least \$57,18319,362 in charges associated with NSIs over the 4-year period.

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3 49 • Introduction of SED in an hospital should be accompanied by education, detailed
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5 50 information, and training of healthcare workers to encourage utilization of the device.
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10 52 **Strengths and Limitations**

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12 53 • A notable strength of this work is that it addresses the International Healthcare Worker
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14 54 Safety Center March 2012¹ call to action to address a lack of new progress in NSI rates.
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16 55 The study identifies a new area where significant progress may be made to reduce
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18 56 sharps injuries worldwide.
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21 57 • A significant limitation is that the study is currently limited to a single US tertiary care
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23 58 site.
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27 60 Keywords: needlestick injury; sharps injury; safety-engineered device; healthcare worker injury;
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29 61 central venous catheter
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34 63 **ABSTRACT**

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38 65 Objective: This article sought to define whether an alternative safety engineered device (SED)
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40 66 could help prevent needlestick injury (NSI) in healthcare workers (HCWs) who place central
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42 67 venous catheters (CVC).
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45 68 Design: The study involved three phases: 1) A retrospective analysis of de-identified
46
47 69 occupational health records from our tertiary care urban US hospital to clearly identify NSI risk
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49 70 and rates to HCW during invasive catheter placement; 2) Ninety-five residents were surveyed
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51 71 regarding their knowledge and experience with NSIs and SEDs. 3) A random sample of six
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53 72 residents participated in a focus group session discussing barriers to use of the SED.
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55 73 Setting: A single urban US tertiary care teaching hospital.
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3 74 Participants: A retrospective analysis of NSI to HCW in a tertiary care urban US hospital was
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5 75 conducted over a 4-year period (July 2007–~~June~~^{July} 2011). Ninety-five residents from specialties
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7 76 that often place CVC during training (surgery, surgical subspecialties, internal medicine,
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9 77 anesthesia and emergency medicine) were surveyed regarding their experience with NSIs and
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11 78 SEDs. A random sample of six residents participated in a focus group session discussing
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13 79 barriers to use of the SED.
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16 80 Results: 314 NSIs were identified via occupational health records. Sixteen percent (21 of 131) of
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18 81 NSIs occurring in residents and fellows occurred during securement of an invasive catheter
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20 82 such as a CVC. If an SED device had been used, these 5.25 NSIs/year could have been
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22 83 avoided. Each NSI occurring in an HCW incurred ~~an estimated average direct cost of \$922~~
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24 84 at least \$2,723 in charges. Thus, utilization of the SED could have saved a minimum of
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26 85 \$57,183~~49,362~~ over the 4-year period.
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29 86 Conclusion: SEDs are currently available and can be used as an alternative to sharps. If safety
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31 87 and efficacy can be demonstrated, then implementation of such devices can significantly reduce
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33 88 the number of NSIs.
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38 90 There is no additional data available
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42 92 **INTRODUCTION**

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45 93 Needlestick or sharps injuries (NSIs) among healthcare workers (HCWs) are a common and
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47 94 potentially avoidable injury. An estimated 600,000 to 800,000 percutaneous injuries occur
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49 95 annually among HCWs in the United States². As high as these estimates appear, the literature
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51 96 indicates that sharps injuries are significantly underreported³⁻⁵. These injuries place HCWs at
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53 97 risk for blood-borne infections and result in considerable psychological distress. In addition, the
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3 98 healthcare system incurs substantial costs from the occupational health testing, prophylaxis,
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5 99 and follow-up that must be implemented for each reported NSI.
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10 101 Safety-engineered devices (SEDs) are promising design innovations intended to prevent
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12 102 hazards and accidents. In medicine, numerous engineering controls have been introduced to
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14 103 decrease the incidence of NSIs among HCWs, including safety-winged steel needles, safety
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16 104 intravenous catheter insertion needles, and many others.
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23 106 The StatLock device (Bard Access Systems, Salt Lake City, UT) (Figure 1) is an SED designed
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25 107 to prevent NSIs during placement of central venous catheters (CVCs). It is a locking device that
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27 108 secures CVCs to the skin with benzoin adhesive instead of the traditional method of using
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29 109 sutures to secure CVCs to skin. Traditionally, after a CVC is placed the patient may require
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31 110 additional local anesthesia in a site separate from the insertion site, necessitating the use of a
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33 111 hollow-bore needle for lidocaine injection. Then, a straight suture needle is used to suture the
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35 112 CVC to the patient's skin. After making a knot with the suture, the ends are then cut with a
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37 113 scalpel. Therefore, using the SED minimizes the risk of NSI during securement of CVC by
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39 114 eliminating three steps during which sharps are used. Despite the easy availability of the
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41 115 StatLock device, few resident physicians are aware of it and fewer still have used it in clinical
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43 116 practice.
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51 118 ~~This SED StatLock device~~ has been available in all adult triple-lumen CVC kits in our urban
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53 119 tertiary care US institution since July 2009. Despite its availability, the ~~SED StatLock~~ is not widely
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55 120 used in clinical practice. The purpose of our study was to perform a needs analysis by
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57 121 retrospectively examining HCW data from our institution to determine whether implementation of
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3 122 the SED would significantly reduce NSIs. We sought to determine whether practitioners did
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5 123 incur NSIs during the securement phase of the CVC procedure, and if this could have been
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7 124 prevented with the use of this SED. Since this SED device has already been readily available in
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9 125 the safety triple lumen catheter kits within the institution, but not yet utilized on a regular basis,
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11 126 we also sought to identify the potential barriers to implementation of a new SED in the
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13 127 healthcare environment. ~~The SED device was readily available in the safety triple lumen~~
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15 128 ~~catheter kits within the institution yet not utilized within the institution.~~
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21 130 We hypothesized that a substantial number of NSIs occur during resident placement of CVCs
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23 131 and could potentially ~~which might~~ be prevented by use of the ~~SED~~ atLock device. However,
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25 132 barriers to the utilization of this SED, including lack of training on the use of the device and staff
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27 133 resistance are likely to impede implementation of safety controls.
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32 33 135 **METHODS**

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35 136 Institutional review board approval was obtained and all NSI data were de-identified. The study
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37 137 was conducted at Hahnemann University Hospital (HUH), an urban tertiary care hospital in the
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39 138 United States. We analyzed retrospective data on all NSIs reported between July 2007 and
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41 139 ~~June~~ July 2011 by HCWs in the adult-care ACGME resident training programs (except
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43 140 neurosurgery).
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49 142 NSI cost was determined by adding the required charges for a “minimal risk” NSI. For the
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51 143 purpose of this study, a minimal risk NSI was defined as an NSI for which the HCW has a low
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53 144 risk for sero-conversion to Hepatitis or HIV viral infection. When this type of NSI occurs, both
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55 145 the HCW and source patient would be tested for HIV and Hepatitis B and C immediately after
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3 146 the NSI. The sum of the charges for the required occupational health appointments and initial
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5 147 lab tests represents the lowest possible cost of a NSI in USD. When the potential risk of
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7 148 transmission of Hepatitis or HIV infection is considered greater, the HCW may be prescribed
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9 149 prophylactic medications and requires repeat tested at regular intervals up to a year after a NSI,
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11 150 significantly increasing the costs associated with NSI.
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16
17 152 Ninety-five residents from surgery, emergency medicine, internal medicine, and anesthesia
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19 153 programs, the disciplines responsible for CVC placement at our institution, were identified and
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21 154 enrolled in ~~a prospective longitudinal~~the study: ~~surgery, emergency medicine, internal medicine,~~
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23 155 ~~and anesthesia.~~ All participants signed written consent to participate. ~~A plan for compensation~~
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25 156 ~~was incorporated into the study design to maximize return for 12-month follow-up.~~ Demographic
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27 157 data for each of the residents were collected, including level of training, department, age, sex,
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29 158 race, and handedness. ~~The~~ survey questions were designed to determine residents' prior
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31 159 exposure to NSIs and to evaluate their prior knowledge of and experience with the StatLock
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33 160 device.

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37 161 ~~Each resident was randomly assigned to either a simulation curriculum or to a standard~~
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39 162 ~~curriculum educational program to familiarize them with the SED device application, and all~~
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41 163 ~~agreed to return in 12 months for a repeat questionnaire. The endpoint for the longitudinal~~
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43 164 ~~phase of the study was defined as a difference in NSIs between the groups. This portion of the~~
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45 165 ~~study is still in progress.~~

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48 166 Finally, a focus group of six randomly selected residents was conducted to assess impressions
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50 167 of the device and to identify potential barriers to its implementation. Participants were
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52 168 interviewed by a study investigator (SG) individually and each session was audio recorded with
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54 169 the permission of the participant. During the focus group sessions, participants were asked to
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56 170 discuss their impressions of the SED, and additional thoughts they had on the use of this
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3 171 alternative method as compared to traditional sutures when securing central lines. These
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5 172 discussions were recorded so that they could be later analyzed by two independent study
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7 173 investigators (SG and AB).
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11 12 13 175 **Data analysis**

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15 176 De-identified data on all NSIs occurring at our institution were independently reviewed by three
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17 177 study investigators (SG, AB, CR). All reported NSIs were reviewed and characterized according
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19 178 to occupation of the HCW incurring the injury ([Figure 2](#)) and according to circumstances
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21 179 regarding the injury. ~~Frequency counts of NSIs were tabulated (Figures 2 and 3).~~ Frequency
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23 180 counts of physician NSIs that occurred during a catheter placement such as a CVC, large bore
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25 181 single lumen catheter, dialysis catheter, or arterial catheter line were also reviewed by the same
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27 182 three investigators and compared for agreement in interpretation. After the focus group
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29 183 sessions, two independent study investigators categorized the residents' statements as neutral,
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31 184 positive, or negative observations regarding the StatLock device.
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36 37 186 **RESULTS**

38 39 187 **Retrospective institutional data analysis**

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42 188 Analysis of the retrospective NSI data revealed that physicians (residents, fellows, and
43
44 189 attendings) accounted for 43% (136 of 314) of the total NSIs occurring between July 2007 and
45
46 190 ~~June~~ 2011 ([Figure 2](#)). ~~Resident NSIs accounted for Resident NSIs accounted for~~ 87% (118 of
47
48 191 136) of the total physician NSIs ~~(118 residents, 13 fellows, and 5 attending physicians)~~
49
50 192 occurring during this 4-year period. Analysis of the circumstances surrounding each NSI
51
52 193 showed that 40 NSIs ~~Thirty-one percent of the resident/fellow NSIs injuries (40 of 131)~~ occurred
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54 194 during the placement of CVCs or other catheter lines that required securement to patient skin.
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3 195 Fifty-three percent (21 of 40) of the NSIs that occurred during these procedures occurred
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5 196 specifically while the line was being secured to the patient's skin with a suture needle. This
6
7 197 accounted for 16% (21 of 131) of the total number of resident and fellow NSIs over the 4-year
8
9 198 period. It is possible that 13 additional NSIs occurred during securement of these catheter lines,
10
11 199 but unless our occupational health record specifically documented that the NSI occurred while
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13
14 200 the worker was securing the line to the patient's skin, those data were not included. The
15
16 201 remaining six NSIs that occurred during placement of a CVC or other invasive catheter. An
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18 202 additional six NSIs occurred with the large-bore needle while the physician worker was
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21 203 attempting to cannulate the vessel.
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25 26 205 **Cost analysis**

27
28 206 Given the number of NSIs determined from retrospective analysis, we calculated that use of a
29
30 207 needleless device to secure the CVC could have prevented ~~these~~ 21 NSIs. The cost analysis
31
32 208 estimates that each NSI incurs at least \$2,723 USD in charges at this institution. each costing an
33
34 209 estimated \$922 (average NSI cost incurred at this institution). Costs associated with an NSI
35
36 210 include provider fees for initial and follow-up visits, blood draw and analysis costs, medication
37
38 211 costs, and administrative costs. Table 1 lists the minimal charges associated with a low risk NSI
39
40 212 using data from our institution's Occupational Health Clinic. While the calculations for this
41
42 213 study represent the lowest possible cost of a NSI, the actual cost of a NSI varies from case to
43
44 214 case depending on the circumstances surrounding the NSI, the treatment plan, medication
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46 215 requirements, and frequency of follow-up visits. If the HCW has a high risk exposure to HIV,
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48 216 prophylactic antiviral medications must be prescribed and the cost of the medications, additional
49
50 217 labwork, and frequent followup visits increases the cost of the NSI significantly. The cost
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52 218 estimates also do not include the indirect cost of time lost from work and other indirect financial
53
54 219 and social costs. Eliminating all 21 NSIs that definitively occurred during securement of a
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3 220 CVCline would have translated into a direct cost savings of at least \$57,183 in USD
4
5 221 charges \$19,362. If the possible additional 13 NSIs also that possibly occurred during the
6
7 222 securement phase where three sharps are included in the calculation (hollow bore needle for
8
9 223 repeat anesthesia, suture needle, and scalpel), were also prevented, the cost savings would be
10
11 224 at least this would translate to a direct cost savings of \$31,348 \$92,582 over the 4-year period.
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226 Enrollment survey of residents enrolled into the longitudinal study

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19 227 The prospective portion of the study surveyed 95 residents. Only Of the 95 residents surveyed,
20
21 228 only 30% had previous knowledge of the needleless SED that is supplied in all CVC safety kits
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23 229 at our institution. Only 19% had ever had training regarding the use of any SED or used the
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25 230 device in clinical practice. Twenty-seven percent of residents surveyed stated that they had had
26
27 231 at least one close call needlestick incident in the past 2 months. And 20% of the residents
28
29 232 surveyed had at least two near miss/close call needlestick incident in the past 2 months. (Figure
30
31 233 4). Twenty-five percent of responding residents (24 of 95) answered yes when asked the
32
33 234 question, "Have you ever had a needlestick injury associated with patient body fluid exposure?"
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35 235 In a follow-up question, we asked, "Did you report the incident each time?" Twenty-one percent
36
37 236 (5 of 24) responded that they did not always report NSI. This finding is consistent with prior data
38
39 237 suggesting that HCW NSIs are underreported³⁻⁶. Forty-nine percent of residents surveyed
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41 238 stated that they had had at least one near miss/ close call needlestick incident in the past 2
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43 239 months (Figure 4).
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241 **Focus group data**

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53 242 Data from discussions with six randomly selected study participants are presented in Table 2.
54
55 243 Statements regarding each residents' experience with Statlock were categorized into positive,
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3 244 negative, or neutral. Opinions of the SED and experiences varied across participants. In
4
5 245 general, those residents who were comfortable and adept at suturing, especially surgical
6
7 246 residents, seemed to prefer using sutures over the Statlock device. According to the responses,
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9
10 247 the use of the SED may also be dependent on patient characteristics, situational circumstances,
11
12 248 and knowledge or acceptance of the SED by other HCWs. One resident indicated that she
13
14 249 would want additional practice with the device before using it in a clinical setting, suggesting that
15
16 250 additional training may encourage increased use of the SED.

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19 251 ~~Focus group discussions were conducted with six randomly selected study participants.~~
20
21 252 ~~Participants were interviewed by a study investigator (SG) individually and each session was~~
22
23 253 ~~audio recorded with the permission of the participant. Focus group sessions lasted an average~~
24
25 254 ~~of 30 minutes to discuss participant use of the StatLock device, their impressions of the SED,~~
26
27 255 ~~and additional thoughts they had on the use of StatLock over traditional sutures when securing~~
28
29 256 ~~central lines. Audio data were extracted and analyzed by two independent study investigators~~
30
31 257 ~~(SG and AB). Focus group data are presented in Table 1.~~

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37 259 ~~Responses varied across participants. One surgery resident noted that surgeons especially are~~
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39 260 ~~more familiar with suturing than with applying StatLock and may be able to secure a CVC faster~~
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41 261 ~~using sutures. The resident stated, "Time is of the essence. [I] don't want to wait for StatLock to~~
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43 262 ~~dry when sutures are faster, more efficient, more comfortable." Another resident who is also~~
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45 263 ~~comfortable and adept at suturing lines mentioned that she would want more practice with~~
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47 264 ~~applying the StatLock device before using it in a clinical setting.~~

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53 266 ~~One emergency medicine resident described himself as "motivated to use StatLock after~~
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55 267 ~~witnessing multiple coworkers experience fingersticks." After using the StatLock device just one~~
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57 268 ~~time, he found the placement of the StatLock device was quicker than suturing the CVC.~~

269
270 ~~Two of the six residents reported that they valued the StatLock device in certain situations when~~
271 ~~they were more likely to incur an NSI, such as when the patient is unpredictable or unwilling to~~
272 ~~lie still. One resident reported that in such cases it is “beneficial to use as few sharps as~~
273 ~~possible.”~~

274
275 ~~Half of the residents were hesitant to use StatLock in certain circumstances because they~~
276 ~~thought that the nurses and other practitioners lacked knowledge about the device. After~~
277 ~~securing a CVC using StatLock in the emergency department, one resident reported, “The~~
278 ~~admitting team was confused, did not know what the device was, and [was] concerned over~~
279 ~~whether StatLock would stay in place.”~~

280
281 ~~One resident pointed out that the StatLock device may be beneficial in certain populations of~~
282 ~~patients. “[StatLock would be] beneficial cosmetically when placing an upper neck line next to~~
283 ~~the face, especially for patients who form keloids.”~~

284
285 ~~Audio-recorded focus group text was transcribed and data were extracted and categorized as~~
286 ~~neutral, positive or negative observations regarding the StatLock device.~~

287

288 **DISCUSSION**

289 In 2009 we developed a partnership with our institutional industrial hygienist to investigate
290 opportunities to reduce NSIs among resident physicians in our institution. In the fiscal year
291 between 2008 and 2009, nurse NSIs increased 10% and physician NSIs increased 70% at our

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3 292 institution. In 2009 at HUH, 46% of the total reported NSIs involved residents. A 2007 study of
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5 293 699 surgical residents at 17 US medical centers found that by the 5th year of residency, 99%
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7 294 had had at least one NSI. Moreover, for 53% of respondents, the NSI had involved a high-risk
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10 295 patient with a history of HIV infection, hepatitis B or C virus infection, or injection drug use.² In
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12 296 2009, our US-based urban hospital reported 27.6 injuries per 100 occupied beds, which is
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14 297 above the EPINet average of 20.1 for teaching hospitals⁷. Despite increased awareness of
15
16 298 sharps injuries and some attempts at prevention, NSIs continue to be a serious problem. Our
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18 299 study supported earlier research findings that among HCWs, physicians have the highest risk of
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20 300 NSI^{2, 10}, and among physicians, residents have a three times greater risk of blood and body
21
22 301 fluids exposure than senior doctors¹¹. These data were alarming and required immediate
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24 302 analysis for the potential for intervention.
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30 304 In medicine, engineering controls that have been introduced to decrease the incidence of NSIs
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32 305 among HCWs include safety-winged steel needles, safety intravenous catheter insertion
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34 306 needles, polyester film-coated capillary tubes, safety-shielded phlebotomy needles, needleless
35
36 307 blood transfer devices, safety peripherally inserted central catheter stylets, blood gas needle-
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38 308 holding devices, blunt-tip needles, and shielded hypodermic needles/syringes⁸. Current
39
40 309 literature indicates that 29% to 35% of reported occupational NSIs could have been prevented if
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42 310 an SED had been used⁹. Although engineering controls may require capital investment, the
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44 311 cost savings resulting from improved safety may justify the expense. However, devices that
45
46 312 depend on user activation generate benefit only when correctly used; thus HCWs must be
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48 313 educated in their use.
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55 315 For some HCW their lack of training and their unfamiliarity with SEDs is a major barrier to its
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57 316 use. ~~The StatLock SED secures CVCs using a locking device attached to the skin using~~
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3 317 ~~benzoin adhesive instead of the traditional method of using sharps. Traditionally, after a CVC is~~
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5 318 ~~placed the patient may require additional local anesthesia in a site separate from the insertion~~
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7 319 ~~site, necessitating the use of a hollow bore needle. A CVC is secured with the use of a straight~~
8
9 320 ~~suture needle and the suture is cut with a scalpel. Therefore, using the SED minimizes the risk~~
10
11 321 ~~of NSI during securement of CVC by eliminating three steps in which sharps are used. Despite~~
12
13 322 ~~the easy availability of the StatLock device, few resident physicians are aware of it and fewer~~
14
15 323 ~~still have used it in clinical practice.~~ Only 30% in our study had previous knowledge of the
16
17 324 needleless SED that is supplied in all CVC safety kits at our institution. Only 19% had ever used
18
19 325 the device in clinical practice. Exposure to the SED and effective training may encourage the
20
21 326 use of SEDs and subsequently reduce NSI. A prospective cohort study using the same 95
22
23 327 residents who participated in this survey has been designed to determine the best means of
24
25 328 educating residents on the use of the Statlock device. Each resident was randomly assigned to
26
27 329 either a standard teaching video or a simulation curriculum involving both the video teaching
28
29 330 plus hands-on practice in a simulated clinical environment. The endpoint for the longitudinal
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31 331 phase of the study was defined as a difference in NSIs between the groups. Additionally, all
32
33 332 participants agreed to return in 12 months for a repeat questionnaire on their attitudes and
34
35 333 experience with the SED. This portion of the study is still in progress. ~~Despite increased~~
36
37 334 ~~awareness of sharps injuries and some attempts at prevention, NSIs continue to be a serious~~
38
39 335 ~~problem. Our study supported earlier research findings that among HCWs, physicians have the~~
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41 336 ~~highest risk of NSI^{2,10}, and among physicians, residents have a three times greater risk of blood~~
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43 337 ~~and body fluids exposure than senior doctors¹⁴.~~

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51 339 In our institution, some physicians-residents who are already familiar with Statlock have been
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53 340 reluctant to use ~~it~~ the StatLock device because they have questions about efficacy and patient
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55 341 safety. Some express concern that the device might not work as well as the traditional method
56
57 342 of securing a CVC to patients' skin using sutures. Many reports in the literature have been
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3 343 authored by individuals associated with the manufacturers, raising the question of potential bias.

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5 344 The StatLock device is currently available in every triple-lumen CVC kit in our institution.

6
7 345 Therefore, the issue of use of the device does not rest on its availability, but rather on physician

8
9 346 awareness, training, and preference.

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14 348 Focus group discussions revealed that such factors have indeed presented barriers to

15
16 349 implementation of the ~~StatLock device~~. Residents expressed concern regarding time

17
18 350 constraints and familiarity with device. Previous literature has documented similar barriers to

19
20 351 implementation. Cost, personnel time, and resistance to change are several of the most

21
22 352 commonly documented deterrents.^{6, 12-16} Surgeons and anesthesiologists have been

23
24 353 recognized as the cohorts least likely to use safety devices designed to prevent NSIs,

25
26 354 presumably because they are skilled at suturing.¹⁷ Reluctance may also stem from feelings of

27
28 355 discomfort and questions of efficacy.¹⁷ Evidence-based reasoning is often absent from the

29
30 356 foundation of implementation programs, exacerbating opposition to change.¹⁸ Perpetual access

31
32 357 to conventional sharps also hinders implementation of safety devices.¹⁹

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36 359 Some institutions have recognized that simple logistics can prevent staff from using safety-

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38 360 engineered devices. Contractual purchasing agreements can render devices unavailable and

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40 361 certain devices may not be compatible with existing equipment^{6, 16}. The overabundance of SEDs

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42 362 on the market makes it difficult for institutions to choose¹⁵, yet most devices are not applicable

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44 363 for all situations and technology must become more advanced to meet the remaining

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46 364 demand.^{15,18}

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50 366 Lastly, HCWs are characterized as being desensitized to disease and consequently possessing

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52 367 a false sense of security regarding the effects of NSIs.¹⁷ When this complacency is coupled

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3 368 with a lack of multidisciplinary support, both “horizontally and vertically,” implementation of
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5 369 safety devices becomes extremely difficult.²⁰
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9 371 **CONCLUSIONS**

10 372 The common incidence of ~~NSIs-needlestick injuries~~ among healthcare workers clearly indicates
11
12 373 a need for further intervention. ~~Retrospective analysis of institutional records demonstrated that~~
13
14 374 ~~over a 4-year period (July 2007–June 2011), 16% of resident/fellow NSIs (21 of 131) could have~~
15
16 375 ~~been avoided with the use of a needleless securement device such as the Statlock device.~~
17
18 376 ~~Engineering controls such as While such SEDsneedleless securement devices~~ are currently
19
20 377 available, ~~they are infrequently used by HCWs for various reasons. -and can be used as an~~
21
22 378 ~~alternative to sharps. Retrospective analysis of institutional records demonstrated that over a 4-~~
23
24 379 ~~year period (July 2007–July 2011), 16% of resident/fellow NSIs (21 of 131) could have been~~
25
26 380 ~~avoided with the use of a safety-engineered device such as the Statlock device to secure a~~
27
28 381 ~~CVC. The implementation of an SED in an institution requires proof of safety and efficacy as well~~
29
30 382 ~~education and training of healthcare workers to encourage the use of the device andIf safety and~~
31
32 383 ~~efficacy of the device can be demonstrated, then implementation of such devices may~~
33
34 384 ~~significantly~~ reduce the number of ~~NSIsneedlestick injuries~~ among physicians. ~~However,~~
35
36 385 ~~education alone will not be sufficient to overcome barriers to implementation.~~
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51
52 391 data; writing of the report; nor the decision to submit the paper for publication.
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55 392

57 393 **Contributorship**

1
2
3 394 Dr Griswold-Theodorson had access to and takes responsibility for the integrity of the data and the
4
5 395 accuracy of the data analysis. Dr Griswold-Theodorson: contributed to study conception and design,
6
7
8 396 data collection, analysis and interpretation of the data, drafting of the manuscript, and critical revision
9
10 397 of the article for important intellectual content.

11
12 398 Ms Bonaroti: contributed to study design, data collection, data analysis and interpretation, reviewing
13
14 399 and editing of the manuscript, and critical revision of the article for important intellectual content.

15
16
17 400 Mr Rieder: contributed to study design, data collection and analysis, review and editing of the
18
19 401 manuscript.

20
21 402 Mr Erbayri: contributed to study design, data collection and analysis, review and editing of the
22
23 403 manuscript.

24
25
26 404 Dr Parsons: contributed to study design, data collection, data analysis and interpretation, reviewing,
27
28 405 editing, and section writing of the manuscript.

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31 406 Dr Nocera: contributed to study design, data collection and data interpretation, reviewing, editing,
32
33 407 section writing of the manuscript and critical revision of the article for important intellectual content.

34
35 408 Dr Hamilton: contributed to interpretation of the data, reviewing, and editing of the manuscript and
36
37 409 critical revision of the article for important intellectual content.

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41 411 **Data Sharing**

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44 412 There is no additional unpublished data.

45 46 47 413 **Competing Interests**

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49
50 414 None

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2
3 416 Figure 1. Right infraclavicular subclavian triple-lumen catheter secured with StatLock needleless
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5 417 device (Bard Access Systems, Salt Lake City, UT). The StatLock needleless device replaces
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7 418 the need for suturing with a locking device secured with benzoin and tape.
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10 419 Figure 2. NSI injury at Hahnemann Hospital by occupation from four year period: July 1, 2007 to
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12 420 June 30, 2011. MD includes residents, attendings, and fellows. Nurse: includes nurses, nurse
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14 421 anesthesia, and nurse practitioners. Others include respiratory therapy, environmental services,
15
16 422 laboratory personnel and others not categorized above.
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20 423 ~~Figure 3. Needlestick injuries while inserting CVC or other invasive catheter requiring sutures at~~
21
22 424 ~~Hahnemann University Hospital for the 4 year period July 1, 2007 to June 30, 2011.~~
23

24 425 Figure 4.3. Close calls involving needlestick injuries witnessed in the 2 months preceding survey
25
26 426 administration in July 2011.
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28

29 427 Table 1. Minimal charges associated with a low risk needlestick injury at Hahnemann Hospital.
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32 428 Table 24. Data extracted from discussions with six randomly selected focus group participants.
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