

Driving Practice Change Through Technology Adoption and Assessment: Clinical and Economic Impact of the Clave® Needlefree System

1

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OBJECTIVES

Practice change can be driven by numerous factors, including opportunities for cost savings, the development of procedures with improved clinical outcomes, the identification of inefficient processes and the availability of new technologies offering clinical benefits.

This case reports on the implementation of the Clave® needlefree intravenous administration system, its effect on clinical nursing practice (including safety), associated patient benefits and its economic impact at St. Joseph's Health Care (SJHC) in London, Ontario. SJHC consists of five facilities with a combined total of almost 1,900 beds and 5,500 employees. This case also illustrates the benefits of evaluating the results of technology implementation and associated processes to identify opportunities for clinical practice change.

SETTING

Needle-stick or sharps injury is a common occurrence among healthcare professionals and a significant health risk, especially for nurses and laboratory workers. Canadian Centre for Occupational Health and Safety (CCOHS) data indicate that some hospitals report one-third of nursing and laboratory staff suffer needle-stick injuries annually (CCOHS 2004). Whenever systems containing needles are used, disassembled or discarded, healthcare professionals risk accidental needle-stick injury. Working with intravenous (IV) equipment has been identified as an important source of needle contact for healthcare workers (P. Thompson, personal communication, December 8, 2000).

Needle-stick injury carries the possibility of exposure to any of more than 20 blood-borne illnesses (Alam 2002). The most clinically significant of these illnesses are hepatitis caused by the hepatitis B virus (HBV) or the hepatitis C virus (HCV) and acquired immunodeficiency syndrome (AIDS) due to the human immunodeficiency virus (HIV). Needle-stick exposure to HIV, HBV or HCV is termed a high-risk exposure. Immunization against HBV can reduce illness associated with this virus and post-exposure prophylaxis (PEP) is available to reduce the risk of both HIV and HBV infection. However, these approaches do not eliminate the risk of viral transmission, and no available vaccine or prophylactic regimen can reduce the risk of disease with HCV exposure. As a result, prevention of needle-stick injury is a key occupational health objective.

Further, employers have a responsibility to provide a safe and healthy workplace. In Ontario, the Ministry of Health and Long-Term Care (MOHLTC) requires hospitals to provide a safe environment, and the MOHLTC is currently reviewing existing guidelines for needle-stick injury prevention. The Needlestick Safety and Prevention Act (National Conference of State Legislatures 2000), passed in October 2000 in the United States, requires employers to

2

- review and update existing plans to control exposure to bloodborne pathogens to reflect technological advances that eliminate or reduce exposure to these pathogens
- document consideration and implementation of appropriate commercially available and effective safer medical devices

Needlefree technology for intravenous administration has become increasingly advanced and available over the last decade. As a result of the need to reduce needle-stick injury and the broader availability of this technology, healthcare institutions are moving toward broader implementation of needlefree systems.

SEQUENCE OF EVENTS

In 1997, SJHC began assessing needle-stick injuries (the most common type of employee injury) in more detail than previously. From 1997 through 1999, SJHC averaged 93 reported needle-stick injuries annually. In 2000, the year the Clave® system was implemented, the number dropped to 68. The true incidence may be higher, as the literature demonstrates that under-reporting of needle-stick injuries is, however, common, with one study finding a range of 29–61% underreporting of needle-stick injuries (Ippolito et al. 1997). In addition, the SJHC figures do not include needle-stick injuries to physicians, medical and nursing students and contract workers.

From 1986 to 2000, SJHC experienced 21 HIV exposures, fortunately without the occurrence of seroconversion. However, the process for managing a high-risk exposure, including PEP with a cocktail of antiviral drugs with significant side effects, can have substantial physical, psychological and emotional effects on the involved individual, family members and co-workers (Hurwitz et al. 1999). Management of high-risk exposure is also associated with a substantial institutional cost.

The Clave® System

The Clave® system is an integrated needle-free IV administration system consisting of IV delivery tubing, connectors, a vial adaptor and a bag access spike.

- Clave® intravenous connector: a one-piece valve that maintains a closed system, reducing the risk of introducing bacteria when infusing medication or withdrawing blood. The connector cannot accept a needle, forcing compliance with needlefree systems.
- CLC2000 catheter connector: a connector that uses the principles of positive displacement, preventing retrograde blood flow into the catheter lumen, eliminating the need to clamp catheters and reducing the risk of catheter occlusion.
- Vial adapter: a closed system, preventing vial contamination
- Bag access spike: technology with an inline back-check valve allowing withdrawal from the bag but no infusion into it, providing a microbial and mechanical barrier to contamination.

At SJHC, an organizational culture of shared leadership governance encourages decision-making involvement of users, in this case, front-line nurses. SJHC formed a multidisciplinary steering committee to evaluate needle-free and safety needle technology as the first step in what became a city-wide initiative to standardize needle-stick prevention technologies. The committee included representation from pharmacy, nursing at two SJHC sites, health and safety, product evaluation and healthcare materials management services (HMMS).

Needle-stick injuries associated with IV systems were neither high-risk exposures nor the most common type of needle stick. However, the amalgamation of existing contracts created an opportunity to standardize IV needle-free systems, and the decision was made

to proceed with standardization. Nurses from all clinical areas participated in product evaluation. Based on user assessment of function, safety, application, quality and ease of use, the steering committee selected the Clave® system (see The Clave® System). In addition, users expressed a strong preference for integrated sets over needlefree components that could be used with existing IV systems. The SJHC clinical network of directors and vice-presidents strongly endorsed the choice.

Implementation began with identification and training of a key nurse in each unit or department and was followed by staff training. In June 2000, SJHC introduced the Clave® needlefree intravenous system. The actual exchange of IV equipment was performed on one day throughout the entire hospital. After implementation, a task force was formed to identify opportunities for practice or policy changes and cost savings.

OUTCOMES

A variety of outcomes were used to evaluate the Clave® implementation:

- a central line study focused on practice changes
- an economic assessment of the switch
- two post-implementation surveys
 - a key nurse survey
 - a user evaluation survey
- needle-stick injury rate tracking

RESULTS

Central Line Study

The central line study was accompanied by a comprehensive review of clinical practice related to management of central lines (see Primer: Central Lines and Heparin). The study was conducted at St. Joseph's Hospital, the acute care site of SJHC, over a three-month period on one inpatient surgical unit that used central venous access devices (CVADs). The study, which included 29 patients, evaluated the following hypothesis:

- if a central line has the CLC2000 adapter in place
 - saline can be used to flush this line, rather than saline plus heparin, without increasing the occlusion rate
 - the interval between flushes can be extended from 8 to 24 hours without increasing catheter occlusions

Primer: Central Lines and Heparin

One important application of needlefree systems is use with central venous access devices (CVADs), commonly referred to as central lines. CVADs include a variety of indwelling catheters, such as the peripherally inserted central catheter (PICC) and the Hickman catheter, which are used to maintain long-term vascular access to the superior vena cava in a range of patient types. The intermittent CVAD, which can have up to three ports, is essential to clinical practice today to deliver a variety of chemotherapeutic agents and parenteral alimentation and to withdraw blood in patients requiring long-term therapy. Intermittent CVADs are, however, associated with the development of various complications, including infection, phlebitis, thrombosis and catheter occlusion (Teichgraber et al. 2003; Todd and Hammond 2004).

The risk of catheter occlusion is reduced by regularly flushing ports with heparin and saline, but heparin use is itself associated with a potentially serious condition called heparin-induced thrombocytopenia (HIT). HIT is an antibody-mediated condition that occurs in 1–5% of patients receiving therapeutic doses of heparin (Kadidal et al. 1999; Spinler and Dager 2003). It also occurs in patients receiving much smaller doses of heparin, but the incidence is unknown (Kadidal et al. 1999). The most clinically significant consequence of HIT is vascular occlusion due to thrombosis, which may result in amputation (20%) or mortality (30%) (Picker and Gathof 2004).

The study captured a variety of data, including flush frequency, the incidence of line occlusions, the cost of supplies and flushing agents. During the study period, no catheter occlusions occurred in lines managed according to protocol, but two occlusions occurred in lines that were inappropriately clamped. As a result of this study, clinical management of peripherally inserted central catheters (PICCs) was also evaluated.

Reviewing the management of central lines after Clave® implementation and performing the central line study had a significant impact on clinical practice at SJHC. Specifically, a teaching package for PICC lines, a new documentation tool and a CVAD reference guide were developed, and care of PICC lines was decentralized from the IV team to nurses on medical and surgical units. In addition, the following clinical practice changes were made:

- use of the CLC 2000 connector with all intermittent central line ports
- changes in flushing protocols for central lines:
 - triple lumen ports: flushed with saline only, with interval between flushes extended from 8 to 24 hours (or after each use)
 - Hickman lines: flushed once per week (or after each use) with saline only
 - PICC lines: flushed every 24 hours (or after each use) with saline only
 - use of a bag access spike with a back check valve to withdraw saline from the IV bag,

- rather than using a vial of saline and a needle to obtain saline to flush the line
- use of the bag for 72 rather than 24 hours, as the back-check valve in the bag access spike prevents contamination of the bag

The practice changes are accompanied by the following benefits:

- eliminating heparin from flushes eliminates the risk of HIT associated with flushing lines and can improve patient outcomes
- reducing the frequency of line flushes decreases nursing time and patient disruption
- eliminating inefficiencies simplifies practice
- all of these changes produce cost savings

Finally, the impact of the Clave® system on IV-related infection was assessed retrospectively. The assessment found that the incidence of line infections did not increase with the protocol changes, including the increased duration of use of the saline bag.

ECONOMIC ASSESSMENT

5

An evaluation of the economic implications of implementing the Clave® needlefree system switch was performed in 2004. This evaluation included costs associated with maintenance of central lines, the economic impact of a high-risk needle-stick injury and the direct costs of seroconversion. Costs associated with peripheral IV lines are not included in this evaluation.

Costs Associated with Maintenance of Central Lines

A detailed review of the process for flushing central lines was performed prior to implementing the Clave® system and compared with the process that was used after the PRN connector was replaced by the CLC2000 (see Table 1). The review not only itemized the supplies and tasks required, but also generated a more efficient process. Prior to Clave® implementation, supplies included needles, syringes, swabs, vials of saline and heparin, and a PRN adapter. After Clave® implementation, needles were no longer required, and the need for syringes and swabs was decreased. Heparin vials were no longer needed, and saline vials were replaced by less expensive saline from the IV bag, withdrawn using a bag access spike. Both the time required to flush a port and the flush frequency were decreased. Finally, the PRN adapter was replaced with the CLC2000.

Overall, Clave® implementation substantially reduced costs associated with flushing central lines. The cost of supplies was reduced by more than \$12,500 and the cost of labour by more than \$50,000, providing a total savings of \$63,092.18, an 87% reduction compared with the initial process (see Table 2). This cost savings is based on annual costs associated with maintaining 20 central line ports daily in one ward. All costs are included, including those associated with changing the PRN adapter every 72 hours and the CLC2000 every seven days. The overall reduction in nursing time was 11 minutes per port per day. Improving process efficiency eliminated 4.5 minutes of this time, whereas implementing the CLC2000 and reducing flush frequency eliminated a further 6.5 minutes. It is important to remember that the savings in this analysis relate only to central lines and only to one representative ward at St. Joseph's Hospital. Total savings can be approximated by estimating the annual number of

Table 1. Process steps associated with central line flushes and changes resulting from Clave® implementation

Process Steps	Pre-Clave Process	Post-Clave Process
Gather supplies	one 10-mL syringe one 5-mL syringe one 18-gauge needle one 21-gauge needle two chlorhexidine swabs one alcohol swab one 10-mL vial heparin 100 ug/mL one 10-mL vial 0.9% saline	one bag 0.9% IV saline one 10-mL syringe one bag spike one alcohol swab one chlorhexidine swab
Prepare syringes	swab vial draw up 10 mL 0.9% saline swab vial draw up 1 mL heparin	swab bag spike with alcohol draw up 10 mL 0.9% saline replace cap on syringe end
Take to bedside	wipe connector with chlorhexidine attach 10 mL syringe with 0.9% saline open clamp – flush remove syringe dispose of needle attach syringe with heparin flush – clamp on positive pressure remove syringe dispose of syringe and needle document	wipe connector with chlorhexidine attach 10-mL syringe with 0.9% saline flush dispose of syringe document

Table 2. Clave implementation: Savings associated with process changes related to central line flushes*

Cost Category	Pre-Clave Process		Post-Clave Process	\$ Savings compared with initial	% \$ Savings compared with initial
	Initial	Optimized			
Supplies	\$16,999	\$16,999	\$4,496	\$12,503	74%
Time/port [†]	4 min	2.5 min	1 min	na	
Time/port/day	12 min (3 flushes/day)	7.5 min (3 flushes/day)	1 min (1 flush daily)	na	
Nursing labour cost/year ^a	\$55,188	\$34,493	\$4,599	\$50,589	92%
Total	\$72,187	\$51,491	\$9,095	\$63,092	87%

[†]Calculations are based on flushing 20 ports on one ward for one year. ^aLabour cost (nursing time is \$28/hr plus benefits) associated with preparation and bedside flush time for 20 ports daily for one year on a surgical ward.

central lines in an institution or clinical network and extrapolating the calculations based on appropriate estimates.

Management of central line occlusion has not been included as a cost factor, as appropriate use of the CLC2000 is not associated with catheter occlusion due to thrombosis. In addition, occlusion data had not been collected before Clave® implementation, so it was not possible to determine the magnitude of the decrease. However, the medication cost alone to manage one line occlusion is \$64/mL of tissue plasminogen activator.

Economic Impact of a High-Risk Needle-Stick Injury

The literature indicates that several categories of costs are associated with high-risk needle-stick injuries (see Table 3). Initial administrative processes and risk management occupy several hours and include the following: rapid initiation of postexposure prophylaxis for HIV, HBV and tetanus; initial laboratory testing for viral antibodies to HIV, HBV, HCV and baseline organ function tests; and employee counselling. Family counselling may also take place. Initial costs amount to \$2,603. Follow-up costs include a set schedule of repeated antibody testing and organ function monitoring over a six-month period, additional employee evaluation and counselling, and hospital administrative costs, for a total of \$713. Employee replacement costs, which include short-term disability costs for 28 days plus the cost of replacement staff, amount to \$13,818. Prevention of high-risk needle-stick injuries can both reduce costs and decrease the psychological and emotional distress associated with these injuries and the risk of seroconversion.

Table 3. Costs associated with high-risk needle-stick injuries*

7

Cost Category	Cost
Initial costs	
Administrative time	\$152
Post-exposure prophylaxis	\$1,863
Laboratory testing	\$307
Counselling	\$281
Subtotal initial costs	\$2,603
Follow-up costs	
Laboratory testing	\$216
Employee evaluation	\$416
Administrative costs	\$81
Subtotal follow-up costs	\$713
Subtotal	\$3,316
Staff replacement costs	\$13,818
Total	\$17,134

*(Bouchard 2002)

Direct Costs of Seroconversion

The direct costs of seroconversion can be substantial (Bouchard 2002), as lifelong suppressive therapy for HIV-infected individuals is required. The Bouchard data from Quebec and from SJHC have been blended to provide an estimate of the direct costs of seroconversion in selected circumstances (see Table 4).

Table 4. Risks and costs of seroconversion*

Virus	Risk	Direct Cost
HBV	2–6%	\$5,511 ^a – \$257,500 ^b
HCV	3%	\$32,564 ^c
HIV	0.3–3% ^d	\$197,361 ^e

*Risk of infection without prophylaxis varies, depending on type of exposure

^a Successful six-week treatment. ^b Unsuccessful treatment and death. ^c Successful six-month treatment. ^d Seroconversion risk 0.3% with subcutaneous exposure and 3% with mucous membrane exposure. ^e Forty-one-week treatment from second trimester.

Post-Implementation Surveys

The key nurse survey, conducted in 2000, found that most staff attended training sessions, but that hands-on experience with the system was necessary to develop a complete understanding of the process. Providing training both before and after implementation contributed to a successful change. Flexibility was necessary to adapt solutions to different clinical units.

The user evaluation survey was conducted in 2001 with 100 nurses, of whom 71 completed and returned the survey. Overall, the survey results suggested a very positive perception of the Clave® system, with 90% of nurses believing that the Clave® system had decreased needle use. Nurses also found the system generally simple to use and compatible with IV products on their units. Responses indicated that the Clave® system had simplified practice and that it was better for patients and safer for staff.

Needle-Stick Injury Rate

Elimination of needle use in IV lines is accompanied by a reduction in needle-stick injuries, simply through a decreased use of needles. Quantification of the decrease at SJHC was complicated by the lack of a prospectively designed study to capture needle-stick data before and after Clave® implementation and by difficulties in separating out institution-specific data. Other institutions, however, have recorded substantial decreases in needle-stick injuries specifically related to IV systems after implementing the Clave® needlefree system (P. Thompson, personal communication, December 8, 2000).

8

DISCUSSION

Since implementation of the Clave® system, SJHC nursing staff has found it to be less intrusive for patients, involving less manipulation of lines, with a decreased risk of endothelial damage, thrombosis and infection. In turn, nursing time related to line maintenance has been reduced, allowing better utilization of staff time. Implementation of the Clave® system has reduced needle handling, thus increasing safety for staff and physicians, and simplified practice, reducing confusion and the amount of equipment required. The clinical study of practice change relating to central lines clearly demonstrated the importance and relevance of clinical research to front-line staff and identified additional clinical processes that could be modified.

Several lessons can be taken from this case:

- Careful evaluation of clinical practice is likely to reveal inconsistencies and inefficiencies that can be addressed through process refinement and education, especially when technology changes are made concurrently.
- Studying clinical practice changes can improve clinical practice and outcomes.
- Although hospitals already collect a large volume of data, it may be impossible to separate specific information retrospectively, such as the rate of needle-stick injuries related to IV systems. Therefore, it is important to plan data collection and evaluation prospectively.
- Substantial cost savings can be derived from apparently small practice changes.

The insights gained to date are providing valuable feedback to the ongoing city-wide initiative of reducing sharps use, needle-stick injuries and the potential for disease transmission in London healthcare institutions. All needlefree systems can improve safety and provide cost savings. However, the Clave® system has unique features that support concurrent clinical practice changes. In the case presented, implementation of the Clave® system enabled the staff at SJHC to assess several concurrent practice changes with the potential to improve employee safety and patient outcomes and reduce costs. **K**

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9

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