Barriers to the Adoption of Safety-Engineered Needles Following a Regulatory Standard: Lessons Learned from Three Acute Care Hospitals

Obstacles à l'adoption des aiguilles sécuritaires conformément à une norme réglementaire : leçons tirées de trois hôpitaux de soins de courte durée



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Abstract

Background: A number of jurisdictions have introduced regulation to accelerate the adoption of safety-engineered needles (SENs). This study examined the transition to SENs in three acute care hospitals prior to and following the implementation of a regulatory standard in Ontario. This paper focuses on the ongoing barriers to the prevention of needlestick injuries among healthcare workers.

Methods: Information from document review and 30 informant interviews were used to prepare three case studies detailing each organization's implementation activities and outcomes. Results: All three hospitals responded to the regulatory requirements with integrity and needlestick injuries declined. However, needlestick injuries continued to occur during the activation of safety devices, during procedures and during instrument disposal. The study documented substantial barriers to further progress in needlestick injury prevention. Conclusions: Healthcare organizations should focus on understanding their site-specific challenges that contribute to ongoing injury risk to better understand issues related to product limitations, practice constraints and the work environment.

Résumé

Contexte : Bon nombre d'autorités ont mis en place des règlementations pour accélérer l'adoption d'aiguilles sécuritaires. Cette étude examine la transition vers l'utilisation d'aiguilles sécuritaires dans trois hôpitaux de soins de courte durée, avant et après la mise en place d'une norme réglementaire en Ontario. Cet article porte sur les obstacles courants face à la prévention des blessures par piqures d'aiguille chez les travailleurs de la santé.

Méthode : Les renseignements tirés d'une revue de la documentation et obtenus auprès de 30 informateurs ont été utilisés pour mener trois études de cas qui présentent les activités et résultats de la mise en œuvre de la réglementation dans chacune des organisations.

Résultats : Les trois hôpitaux ont chacun tenu compte des exigences réglementaires et il y a eu une réduction des blessures par piqûres. Cependant, il y a encore des blessures par piqûres lors de l'activation des mécanismes de sécurité, lors de la procédure et lors de la disposition des instruments. Cette étude a permis de documenter d'importants obstacles à l'amélioration de la prévention des blessures par piqures d'aiguille.

Conclusions : Les organismes de santé devraient se pencher sur les défis qui contribuent aux risques dans leur établissement particulier, et ce, afin de mieux comprendre les enjeux liés aux limites des instruments, aux contraintes pratiques et à l'environnement de travail.

ORLDWIDE IT HAS BEEN ESTIMATED THAT HEALTHCARE WORKERS SUFFER 2 million needlestick injuries annually (Wilburn and Eijkemans 2004). Needlestick injuries have the potential to result in the transmission of bloodborne pathogens (e.g., hepatitis B, hepatitis C, human immunodeficiency virus) between patients and healthcare workers. In 2007, the province of Ontario (Canada) established a regulatory standard requiring the adoption of safety-engineered needles (SENs) in the provincial healthcare system as a measure to reduce the incidence of needlestick injuries (Ontario Regulation 474/07 Needle Safety 2007). Prior to the regulatory standard, a Canadian survey on the health of nurses found that nearly half of the nurses reported being injured by a needle or other medical sharp at some point during their career and 11% within the previous year (Shields and Wilkins 2006). Following the introduction of the regulatory standard, the decline in needlestick injury rates in the province of Ontario has been less than expected (Chambers et al. 2015). Over a nine-year period (2004–2012), needlestick injury rates in Ontario's health and social sector declined by 38%, and by 30% specifically in the hospital sector (Chambers et al. 2015). There was an expectation that the mandatory use of SENs could eliminate up to 90% of injuries in the province (Bill 1279 2005). Controlled studies that have examined the efficacy of SENs have documented considerable variation in outcomes (Lavoie et al. 2014; Tuma and Sepkowitz 2006). Less-than-optimal outcomes have also been documented in other jurisdictions that have established regulatory standards to promote the adoption of SENs (Chambers et al. 2015; Jagger et al. 2008, 2010; Stringer et al. 2011). However, these studies have not provided any contextual information on implementation issues associated with the use of these devices.

This paper presents findings from a qualitative case study that describes the experiences of three Ontario hospitals following the implementation of a regulatory requirement to implement SENs, with a specific focus on describing ongoing barriers to the prevention of needlestick injuries among healthcare workers.

Methods

Design

A qualitative case study design (Stake 2005) was carried out in three acute care hospitals in the province of Ontario, Canada, over a 24-month period (April 2011–March 2013).

Sampling and recruitment

Geographic sampling was used to identify 17 community and teaching hospitals that were within 40 km of our research offices. From this roster, hospitals were randomly sampled to participate.

At each site, staff were purposefully recruited to obtain a broad range of perspectives. Staff that were involved in the implementation of SENs were initially recruited through referrals made by the health and safety staff at each hospital. An e-mail invitation was

distributed to nurses in select departments where SENs were in frequent use, including the emergency department or critical care unit.

Data collection

The two main sources of data used in this study were document records and face-to-face interviews. A range of topics were addressed during the interviews with staff. To examine ongoing implementation efforts, both document records and interviews were used to describe what measures were in place and also perceptions towards ongoing investment in this area. Ongoing needlestick injury risk was understood through analyses of incident reports and through interviews with nurses who were able to comment on their own personal injury experience or those that they had observed in practice.

Informants in the department of occupational health and safety assisted with the collection of supporting documents including: evaluation reports, written policies and procedures, incident reports, inspection orders, safety product lists, training materials and administrative documents from the sharps safety committees.

Data analysis

Case studies were prepared for each hospital site detailing the organization's implementation history, relevant activities and outcomes. The case reports were based on accounts from interviews, observations from field notes and information extracted from organizational documents (Braun and Clarke 2006). A thematic analysis was carried out to identify patterns and themes within and across the three case sites. The analysis considered both retrospective reflections of the implementation experience and reflections on current and future conditions. When analyzing interviews, attention was placed on practices, understandings and conditions at the workplace level, to examine not only what they reported about the use of safer needle technology but how they talked about it. There was also an attempt to think through some of the implications of shared views or divergent perspectives and underlying assumptions through an in-depth review of the accounts.

The research protocol was approved by the ethics review board at the University of Toronto and by ethics review boards at the three participating hospitals.

Results

The complete data set included 30 semi-structured interviews, 55 document summary forms, 36 case summary forms and 32 field notes. The interviews were conducted with healthcare professionals (57%) and hospital managers and administrative staff (43%). Half of the interviews were carried out with staff who currently or previously had a health and safety role in the organization. This paper focuses on two primary themes from the case studies: the influence of technology, practice and the work environment on ongoing needlestick injury risk and organizational constraints to further invest in needlestick injury prevention.

Table 1 summarizes key attributes of the participating hospitals. The three hospitals provided acute care services in cities serving primarily large urban populations. Different types of SENs were available across the three hospitals. Manual SENs, which require the user to directly manipulate the safety component on the device, were available at all three hospitals. Semi-automatic SENs were also in use. These devices have a retractable component but are not considered truly passive, as some form of user activation is required (e.g., press of a button). Hospital C was the only site to integrate fully automatic or passive SENs in select high-risk areas. While needlestick injuries declined following the integration of SENs, there was considerable variation in outcomes. Needlestick injury rates declined by 28%, 60% and 81% at Hospitals A, B and C, respectively.

TABLE 1. Summary of implementation processes and outcomes in the three acute care hospitals

	Hospital A	Hospital B	Hospital C
Characteristics	Large teaching hospital	Multi-site community hospital	Large teaching hospital
Transition to safety needles	2007, in response to safer needle regulation	2006, in response to a workplace inspection order	2003, voluntary transition
Training	Group-based training	Train-the-trainer strategy	Group-based + train-the-trainer strategy
Types of SENs	Mix of semi-automatic and manual	Mix of semi-automatic and manual	Mix of semi-automatic, manual and passive
Ongoing implementation policies and practices	Written policies and procedures	Written policies and procedures	Written policies and procedures
and practices	Ongoing monitoring of incidents	Ongoing monitoring of incidents	Annual review of exceptions
	Resources on the intranet		Ongoing monitoring of incidents
Rate of NSIs per 100 beds			
Time I*	11.9	15.3	8.3
Time 2**	8.6	6.2	1.6
% change	↓28%	↓60%	↓81%

^{*}One year prior to the transition

Pathways for ongoing needlestick injury risk

At all three hospitals, needlestick injuries declined following the implementation of SENs; however, needlestick injuries continued to be documented in incident reports. While Hospital C was observing less than 20 needlestick injuries annually at the time of the field work, both Hospital A and B were continuing to document between 40 and 100 needlestick injuries each year. As healthcare workers reflected on their own injury experiences and injuries that they had observed in practice, they were able to contextualize a number of product limitations and environmental constraints that limited the effectiveness of SENs, including unpredictable patient interactions, downstream risks of exposure and safety device activation and design.

^{**}Three years post-implementation

UNPREDICTABLE PATIENT INTERACTIONS

The most common explanation for ongoing injury risk focused on injuries that occur before SENs are activated, during a procedure and as a result of patient action. In these situations, patients were described as being "aggressive," "combative" or "not-cooperative." The risk of exposure prior to the activation of SENs is heightened as a result of these unpredictable patient interactions. Workers acknowledged how their work environment and interactions with patients can be unpredictable:

Maybe a patient becomes very anxious or just swats their hand very quickly and catches the nurse completely off guard whereas the needle can end up sticking them instead of a patient. Sometimes you really just don't know what may happen and it may not be preventable in a sense because it just happens so sudden.

The notion of being able to evaluate and plan for difficult patient interactions was challenged by workers. One of the nurses recounted her own recent needlestick injury experience to explain how challenging it can be to anticipate these types of interactions. Based on her initial assessment, she had determined that her patient was "compliant" and "coherent." Her injury happened during the second injection; the first injection gave no indication that the patient would resist.

There was a shared perspective that safety needles that needed to be manually activated are limiting in these types of situations. The manual SENs were described by some workers as more challenging to activate. An injured worker recounted her experience using a manual SEN with a patient who was not cooperating with the procedure. This was a safety device that the worker felt was effective in reducing risk of injury only when used in a "contained and stable environment." This pathway for ongoing injury risk represents an important limitation with respect to both the work environment and limitations in the ability of SENs to reduce risk of exposure at all stages of care.

DOWNSTREAM RISK OF EXPOSURE

A number of the organizational informants also linked ongoing injury risk to improper sharps disposal practices, including the use and replacement of overfilled sharps disposal bins. The examples that were provided emphasized how these practices did not only impose a risk of injury to oneself but also to other nurses and housekeeping staff working in the same area. These types of injuries were perceived to be concerning, as the source patient would be unknown, complicating the post-exposure testing protocol. This pathway for ongoing injury risk also draws attention to the lack of control over the work environment, emphasizing the implications of individual practices on the health and safety of co-workers.

SAFETY DEVICE ACTIVATION AND DESIGN

In reference to ongoing needlestick injuries, nurses and managers emphasized not only the potential for needlestick injuries to occur before safety devices were activated but also during activation. The most common SEN in use across all three sites had an active design where a safety cap had to be manually flipped over the needle. The potential for injury arises when healthcare workers attempt to use their finger to flip and lock the safety cap into place rather than using a stable surface such as a bed frame or table to activate the device.

There were a number of incidents described by informants that emphasized that not all SENs are equally effective, easy to use or able to eliminate needlestick injuries. Informants at Hospital A described what they referred to as a "non-functional safety." The device, which was a manual safety butterfly needle, resulted in an increase in needlestick injuries. Staff found the safety device too cumbersome and, thus, the safety component was not being used. Informants attributed the more bulky design of the device as an important contributor to the ongoing injuries that were being reported. It was interesting to note that the needlestick injury data collected from Hospital C demonstrated that needlestick injuries occurring during a procedure actually doubled following the implementation of SENs but then slowly declined over time. These two examples demonstrate the potential for some SENs to be limited in reducing risk of exposure or in some cases requiring a period of adaptation. An important consequence of using manual SENs is that they put a demand on the user to maximize the safety potential of the device. Manual activation can then be hampered by environmental demands and unpredictable interactions.

PERCEIVED CONTROL AND RESPONSIBILITY OVER ONGOING INJURY RISK

There were a number of explanations as to why needlestick injuries continue to occur and how they could be further prevented. These explanations can be organized under two perspectives: the individual blame perspective that emphasized the importance of staff compliance and "being more careful" and the environmental constraints perspective. Explanations that centred on the inevitability of injury were reflected in the accounts above that focused on unpredictable patient interactions, reliance on the health and safety practices of co-workers and product limitations.

The description of ongoing injury risk attributed to proper adherence to the timing of activation eludes to the important role that point-of-care health professionals have in creating a safe work environment. Other references to the importance of staff compliance were more direct. The following quote provides an example of how nurses attributed ongoing injury risk to individual action. In this case, there was an emphasis on the importance of taking personal control over the situation:

I tell nurses you are the one in control, you have the needle in your hand, make sure the patient stays still which means either you hold them still or you tie them down, get another nurse to hold them down because if they flinch, it's going in through him and you.

There were select reports from the informants that described continued poor compliance with the use of SENs. One representative from health and safety who was routinely monitoring injury data emphasized that while usage had improved over time, there were still issues and injuries. Nurses were able to speak to the types of "bad practices" that were ongoing, which were most commonly linked to SENs not being activated prior to disposal. As one nurse emphasized, "at the end of the day the issue isn't what the hospital has, the issue is how the staff use it."

Constraints to further investment in needlestick injury prevention

A common finding across all three hospitals was limited ongoing investment in needlestick injury prevention. Some informants expressed reservations about the value of future investments to promote consistent use of SENs and the need to adopt more advanced SENs. For example, organizational informants at Hospital B felt that the time investment involved in re-examining lists of non-safety needles that continue to be used in select areas would unlikely result in any product changes. Across all three cases, there was no momentum for an increased use of passive safety needles. The following quote is from a worker who did express positive views towards the added value of passive SENs but also emphasized that staff are content with the current stock:

I do think that staff are quite happy with their safety-engineered devices, I am not saying that, that they wouldn't be happier if they have had their retractable, I would certainly think in certain cases it would be better, but what we've got is certainly helping.

Some informants presented a different perspective, expressing strong support for the use of more advanced safer needle technology and the need for more emphasis on needlestick injury prevention. These informants had all recently reported a needlestick injury. Some workers used the interview as an opportunity to share how their own injury could have been prevented with the use of a passive safety device. While this group could be considered "experts" on account of their experience, they did not feel they were in a position of power to advocate for improvements.

Another barrier to furthering prevention efforts in this area was the lack of investment in the ongoing review of needlestick injuries and efforts to share information with staff. There were a number of nurses who were not aware that needlestick injuries were continuing to occur. There was also limited information available to identify where additional prevention efforts should be targeted.

Informants also spoke of "change fatigue" as a barrier to implementing new preventive measures to further reduce injury risk. At Hospital A, where SENs were integrated within a very short period, resistance to change was in part attributed to employees responding

more generally to an overload of changes at the hospital. The following quote is from an organizational informant who felt that the initial resistance to SENs arose in part from working in an environment that is under constant change:

Hospitals are going through so much change right now universally that people are almost balking at anything, people get a little fed up with change so I think that's confounding what they really feel about the product or its safety. If it's something different, it's a change and they don't want it.

Other informants spoke of "change fatigue" as a barrier to considering new SEN technology or to the implementation of additional training opportunities. Perceptions of financial constraints were also a barrier to further prevention efforts. SENs are more expensive than conventional non-safety needles and syringes, and the initial adoption of SENs following the regulatory standard had significant cost implications for hospitals. Occupational health informants noted financial issues were a constraint in their efforts to integrate more advanced safer needle technology at Hospital A and B. Nurses also reported a reluctance to advocate for better technology based on their understanding of constrained hospital resources.

Discussion

A qualitative case study of the implementation experience in three acute care hospitals described outcomes of a hospital-wide transition to SENs and a number of product limitations and environmental constraints that reduced the effectiveness of SENs. Needlestick injuries did decline at all three sites following the transition to SENs; however, a number of injuries continued to be reported. Ongoing injuries following the mandatory use of SENs have been described in a number of jurisdictions (Chambers et al. 2015; Jagger et al. 2010; Jagger and Perry 2003; Stringer et al. 2011; WorkSafeBC 2011) and in studies of SEN efficacy (Lavoie et al. 2014; Tuma and Sepkowitz 2006). As revealed in this study, there are a number of barriers to completely eliminating needlestick injuries under current conditions. There are gaps in the ability of SENs to prevent injuries during activation, during a procedure and during instrument disposal.

With respect to the generalizability of the case study findings to other hospitals in the province, the variation in the outcomes observed across the three cases following the integration of SENs suggests we would see variation in the levels of success with respect to declines in needlestick injuries across hospitals in the province. Despite variation in processes and outcomes, there were consistent themes across the three hospitals specific to implementation challenges, ongoing needlestick injuries and organizational constraints impeding further progress in this area. The consistency of these themes resonated with stakeholder groups who have attended presentations on the case study findings.

It is important to reflect on what can be achieved. Hospital C was able to reach a point where less than 20 injuries were being reported annually. There is likely considerable variation across hospital organizations in terms of the types of SENs provided, the quality of training and other supports, the health and safety culture and various other organizational characteristics (e.g., staffing, workload demands, crowding) that will influence injury risk. There does appear to be opportunities to further enhance prevention in this area, particularly among sites that continue to observe elevated rates of needlestick injuries. There is a need to strive to ensure that healthcare workers across the province have comparable access to the best safety devices and a safe work environment.

There are a number of recommendations that can be made to further needlestick injury prevention for both hospitals that have already integrated SENs and those that are in the process of doing so. In 2013, a European Union (EU) directive on sharps safety came into effect, providing member states three years to adopt the requirements outlined in the framework. There is an opportunity to share best practices and lessons learned regarding effective implementation practices with hospitals that are in the early implementation planning stage. For organizations that are in the process of integrating SENs, there is a need to invest in a comprehensive implementation planning process to support the successful integration of this technology (PSHSA 2012). This might involve looking for guidance on how best to establish an implementation team (The National Implementation Research Network 2015). Multidisciplinary implementation teams should undertake a comprehensive assessment or diagnostic analysis of some of the anticipated barriers and facilitators to practice change across the organization to inform the types of supports that will be needed (Moore et al. 2014).

This study has also suggested that there is a need for organizations who have already integrated SENs to continue to consider needlestick injury prevention as an important occupational health and safety issue and to promote sustained adherence to safer needle use. For example, organizations need to continue to collect sufficient information from ongoing needlestick injuries to identify which of the remaining pathways is most responsible for ongoing injury risk.

Despite a number of gaps in the effectiveness of SENs and ongoing reports of issues with safer needle use, needlestick injury prevention was not reported as an ongoing priority. There was a lack of awareness regarding ongoing injury risk and divergent views over whether ongoing injuries could be further reduced. Perceived financial constraints and competing health and safety priorities also appear to be influencing further progress in this area.

There are a number of small measures hospitals can adopt to continue to enhance prevention in this area, including opportunities to increase awareness that needlestick injuries continue to occur, which may involve opportunities to discuss recent injuries that have been reported during staff meetings to identify opportunities for prevention. The recommendations made here are in line with the Consensus Statement and Call to Action that was drafted by members of a multi-stakeholder steering committee attending the tenth anniversary of the

US Needlestick Safety and Prevention Act (International Healthcare Worker Safety Center 2010). The call to action acknowledged that while substantial progress has been made, preventable sharps injuries and blood exposures continue to occur. They argued that not all issues have been resolved by the enactment of regulatory standards to promote the uptake of SENs and that renewed commitment was needed to achieve further progress.

Conclusion

In conclusion, there appear to be a number of product limitations and environmental conditions that can help explain ongoing reports of needlestick injuries following the implementation of a regulatory standard. It is recognized that investment in this area will be challenged by other important health and safety priorities; however, a renewed interest in needlestick injury prevention among healthcare workers and managers is necessary to make further progress.

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