Title: Safety Engineered Medical Devices: Cost-Effectiveness

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Context and Policy Issues:

The terms sharps is generally used to describe medical instruments or devices that are either hollow bore (e.g., needles for injections and drawing blood) or solid (e.g., suture needles, scalpels, and scissors). A wide variety of such devices are present in health facilities. Each year Canadian health workers suffer injuries related to contact with used sharps, primarily needles. Drawing on a convenience sample of 12 hospitals and relying on passive injury surveillance reports, the Canadian Needle Stick Surveillance Network (CNSSN) estimated a needle stick injury rate of 42/1000 full time equivalents (FTE) in fiscal year 2000/2001. Registered nurses suffered the largest number of injuries (748) but injuries were reported by workers in at least 13 different occupational groupings, the injury rate ranging from 14/1000 FTE for radiology technicians to 428/1000 FTE for lab staff drawing blood (phlebotomists).\(^1\)

The CNSSN data likely underestimate the number of sharps injuries occurring in Canadian health facilities. The CNSSN sample only includes hospitals, considers just one type of sharp injury (i.e., needle sticks) and relies on passive surveillance data which is universally believed to underestimate actual injuries.

Clarke et al. surveyed acute care hospital nurses (n=34,318) from four countries in 1998/1999 in order to compare injury rates, including Canadian nurses from Alberta, British Columbia and Ontario (n=16,285).\(^2\) Respondents were asked how many times they had been injured by used needles or other sharps in the previous year. The results indicate an annual injury rate for Canadian nurses of 251/1000 FTE, more than five times the rate identified for registered nurses in the CNSSN data. The annual injury rate for Canadian nurses varied by nursing specialty, ranging from 102/1000 FTE for nurses working on psychiatry wards to 569/1000 FTE for nurses working in operating rooms and/or perioperative units. In a sub-group analysis of nurses

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working on medical-surgical units, the largest nursing specialty group in the study, Canadian nurses had an injury rate of 209/1000 FTE compared to 146/1000, 157/1000 and 488/1000 FTE in the United States, the United Kingdom and Germany, respectively.

The risk of transmitting blood borne pathogens via sharps injury has heightened awareness and concern regarding such injuries. The risk of occupational transmission depends on numerous factors including the probability an injury may occur, the severity and depth of the injury, the prevalence of a pathogen in the patient population, and, assuming a sharps injury involves an infected patient, the viral load of the injected material.\(^3\,^4\) Many blood borne pathogens can be transmitted via contaminated sharps but concern generally focuses on human immunodeficiency virus (HIV), hepatitis B virus (HBV) and hepatitis C virus (HCV). The average risk of seroconversion following injury by a contaminated needle is estimated at 0.3% for HIV, 1% to 40% for HBV depending on immunization status of the health worker and 1.8% for HCV. In Canada, three cases of occupationally acquired HIV (one confirmed, two probable) have been identified since 1985 with the confirmed case being attributed to a needle stick injury.\(^1\)

Sharps injuries impose financial and other costs on health systems and health care workers even in the absence of seroconversion. Financial costs can include baseline and follow-up serological tests, lost productivity associated with reporting and treating the injury, drug prophylaxis, counseling and, potentially, sick leave. Non-financial costs include the trauma and anxiety endured by injured workers and/or their families.\(^4\) In Ontario the average Workplace Safety and Insurance Board (WSIB) cost for no-lost-time claims related to needle stick injuries is $91 and for lost-time claims, $2,357. Claim counts doubled from 700 to 1,400 between 1999 and 2003. In Ontario, WSIB claim costs in 2004 for needle stick injuries reached $132,000. The full cost of a single needle stick injury in Ontario is estimated to be 6 to 8 times the WSIB cost ($546 to $18,856).\(^5\)

Safety engineered medical devices (SEMDs) are similar in form to conventional sharps but incorporate design features such as a shield or a needle-retracting device that is intended to prevent contact with an exposed needle or other sharp. SEMDs are generally more expensive than conventional devices and cost considerations are often central to debates concerning their adoption.

Reducing sharps injuries requires a hierarchy of control measures including, in order of impact, elimination of the hazard (e.g., use of wound adhesives instead of sutures), engineering controls (e.g., SEMDs), administrative controls (e.g., relevant policies and procedures), work practices (e.g., no recapping of needles) and personal protective devices (e.g., gloves).\(^5\)

Alberta, Manitoba and Saskatchewan have adopted legislation and/or regulations requiring the use of SEMDs in specified settings.\(^6\) Other Canadian jurisdictions will likely experience pressure to adopt similar provisions. There is ongoing interest among decision-makers for information of the impact of SEMDs. The purpose of this report is to retrieve and appraise recent evidence available on the cost-effectiveness of SEMDs in preventing sharps injuries in hospitals.

**Research Question:**

What evidence exists concerning the cost-effectiveness of SEMDs in hospital settings?
Methods:

A limited literature search was conducted on key health technology assessment (HTA) resources, including OVID MedLine, The Cochrane Library (Issue 1, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2003 and February 2008, and were limited to English language publications only. No filters were applied to limit the literature retrieval by study type.

Summary of Findings:

The literature search failed to identify any published or grey literature reporting specifically on the cost-effectiveness of SEMDs in hospital settings. Two systematic reviews (SRs) were identified that include brief reference to the cost-effectiveness of SEMDs based on reports published before the time parameters specified in our search.4,7

Systematic Reviews

Lee et al. reviewed literature published between January 1990 and June 2003 addressing the epidemiologic, economic, health-related quality-of-life and legal aspects of needle stick injuries in hospital settings. The authors identified two studies which they describe as evaluating the cost-effectiveness of SEMDs for preventing needle stick injuries. Little detail concerning the studies is presented. The first study involved a 6-month study comparing a needleless intravenous (IV) access system to a conventional IV heparin-lock system. The results suggested 52 needle stick injuries (no denominator reported) could be avoided annually by hospital-wide adoption of the SEMD. Incremental costs for the SEMD devices were estimated at $82,822 per year, resulting in a cost per injury avoided of $2,571 (currency not specified but presumed to be US$). The second study involved a 12-month prospective pre- and post-intervention study of a safety syringe as well as components of a needleless IV system. Assuming a constant rate of injury, 19 needle stick injuries (denominator = 33) were avoided as a result of the initiative. The cost per injury avoided was calculated at $1,186 (currency not specified but presumed to be US$).4

Tuma et al. reviewed literature published between January 1995 and September 2005 addressing the effect of SEMDs on injury rates. Although the economics of SEMDs were not identified as a primary focus of the review, three studies presenting cost per injury avoided calculations were cited including the two identified by Lee et al. No detail is presented on any of the studies. The authors comment that the ‘cost-effectiveness per injury averted’ is dependent on injury management protocols, the incremental cost of SEMDs, training and education costs, and indirect costs.7

Limitations

The SR authors suggest the studies analyzed in the SRs suffer from serious limitations. They were published 9 to 13 years ago which may place them in closer relative proximity to the emergence of SEMDs than to current practice and technologies. Their designs were generally uncontrolled before-after studies which are unable to assess the impact of confounding variables such as the education and training programs that accompanied introduction of SEMDs. Sample size was too small to achieve adequate power for detection of significant differences, but this is a deficiency that is difficult to overcome in SEMD studies. Methodological concerns include reliance on passive surveillance data to identify changes in the incidence of
injuries, short follow-up periods and a definition of costs that focuses narrowly on the purchase price of SEMDs. Finally, despite the use of the term 'cost-effectiveness' by the SR authors, none of the studies cited can appropriately be characterized as cost-effectiveness analyses.

Assuming the economic studies have been accurately summarized in the SRs, especially the manner in which results are presented (i.e., cost per injury avoided), they would best be described as partial economic evaluations or basic cost analyses rather than cost-effectiveness analyses. The narrow scope of the two studies retrieved by Lee et al represents an additional limitation as these focused on needleless IV systems, which only represent a portion of SEMDs.

**Conclusions and Implications for Decision or Policy Making:**

We were unable to identify formal and complete economic evaluations of any kind concerning SEMDs. Although our literature search covered a relatively short timeframe it is interesting to note that the SR by Lee et al., which explicitly sought economic literature, appears to have been equally unproductive. Together our search strategies span 18 years of published literature and raise the possibility that the economic evidence required to support policy and/or decision makers does not exist.

Given the apparent current lack of full economic evaluations on SEMDs, adoption decisions related to these devices will likely need to be based on considerations other than their economic value. Information on costs and potential budget impact is available. However, evaluation of these would ideally include acquisition costs of SEMDs, as well as indirect (training and, if relevant, maintenance) and societal costs (impact on employability). Evidence on the clinical efficacy of SEMDs in preventing injuries will also be important. Lastly, given the potential consequences of sharps injuries on health, ethical aspects may also need to be considered. The evaluation of such aspects was however beyond the scope of this report.

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