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The impact on central line-associated bloodstream infection rates following the introduction of a closed system transfer device in oncology wards

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SUMMARY

Prevention of hazardous drug exposure is essential in averting unnecessary health risks to health care workers (HCW). To address the risk to HCWs when handling hazardous drugs, engineering controls can be utilized to reduce the exposure. A closed system transfer device (CSTD) was introduced for hazardous drugs administration in 6 oncology wards; this new CSTD was associated with a significant increase in CLABSI rates.

Introduction

Antineoplastic drugs are hazardous drugs used worldwide in healthcare for the treatment of cancerous and non-cancerous illnesses [1]. Prevention of hazardous drug exposure is essential in adverting adverse health affect in healthcare workers (HCW) from occupational exposures [1–3]. To address the risk to HCWs when handling hazardous drugs, engineering controls such as closed system transfer devices (CSTD) can be utilized for preparation and administration of hazardous drugs to protect the HCW from exposure [1–3]. A CSTD is a device that mechanically prohibits the transfer of environmental contaminants into the system and the escape of hazardous drug or vapor concentrations outside the system [2,3].

Outbreaks of central-line associated blood stream infections (CLABSI) associated with the introduction of engineering controls to prevent employee or patient exposures (e.g., needleless adaptors) have been previously reported [4–7].

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After introducing a CSTD in six oncology wards, our facility experienced a significant increase in CLABSI rates. The aim of this study was to determine if the introduction of the CSTD was associated with a temporary significant increase in CLABSI rates.

Methods

This study was performed at a 1,266-bed academic hospital. On 24th October 2016, a CSTD was introduced for hazardous drugs administration on six oncology wards (one haematopoietic stem cell transplant (HSCT) ward, two leukaemia/lymphoma wards, one medical oncology ward, one oncology intensive care unit (ICU), and one gynaecological oncology ward). Infection Prevention (IP) was not notified prior to the CSTD being introduced into use. Pre-implementation, the floor staff received education on the CSTD that included a vendor-led, in-service and online competency module, plus a trouble-shooting guide developed by the oncology clinical nurse specialist. Each ward had multiple nurse super-users, who received additional device education. The super-users completed a checklist with all staff members to ensure correct device handling and were on the wards during implementation. Post-implementation, staff were provided ongoing central line care education.

This was a quasi-experimental study divided into three periods: pre-implementation (1/1/2016-31/10/2016), implementation (1/11/2016-31/12/2016) and post-implementation (1/1/2017-30/9/2017). The hospital IP department conducted routine CLABSI surveillance, using the National Healthcare Safety Network (NHSN) definitions [8]. The NHSN, 2017, blood stream infection event definition was utilized to identify all CLABSIs during the study period to ensure consistent CLABSI identification throughout the study period [9]. Mucosal barrier injuries (MBI) bloodstream infections, as defined by NHSN, were excluded [9]. The CLABSI rate was calculated as the number of infections per 1,000 central line days. CLABSI rates pre-implementation, implementation, and post-implementation were compared using Mantel-Haenszel chi-square analysis. This was determined to be exempt human subject research by the Washington University Human Research Protection Office.

Results

Compared to CLABSI rates in the pre-implementation period [68 CLABSI/34,575 central line (CL) days; rate = 2.0/1000 CL-days], there was a significant increase in CLABSI rates across all oncology wards during the implementation period [22 CLABSI/7,198 CL-days; rate =3.1; P=0.036 vs. pre-implementation] (Figure 1). The pre-implementation CLABSI rate among the six wards ranged between 0.7 (2/2789) per 1000 CL days for gynaecological oncology ward to 2.5 (22/8,797) per 1000 CL days for the leukaemia/lymphoma ward B. During implementation, the CLABSI rates among wards ranged between 0 (0/548) per 1000 CL days for gynaecological oncology ward to 5.4 (7/1274) per 1000 CL days for the leukaemia/lymphoma ward A. Leukaemia/lymphoma ward A and leukaemia/lymphoma ward B drove the increase in CLABSI; the combined rate in these two wards significantly increased from 2.4 (36/14,830) per 1000 CL days during the pre-implementation period to 4.8 (15/3,083) per 1000 CL days during the implementation period (P=0.01).

An investigation by IP was initiated; no other practice changes were noted. IP identified and worked to mitigate several concerns with the CSTD. The CSTD selected was incompatible with the intravenous administration tubing used at our facility; this caused additional manipulation of the

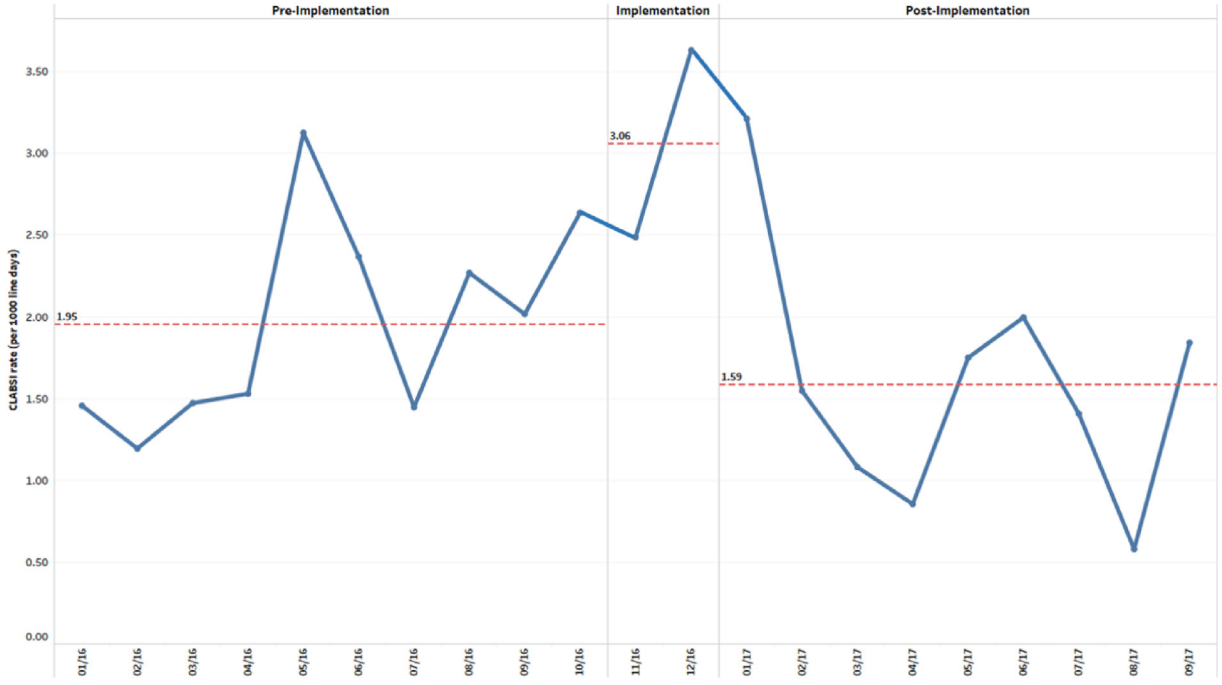

Figure 1. Monthly rate of CLABSI between 1st January 2016 and 17th September 2017 in the six oncology wards during the three study periods.

infusion set-up. After the product implementation, the infusion set-up was found to unexpectedly disconnect at the connection between the CSTD syringe adapter and the intravenous tubing, as well as at the connection between the central line lumen and the needleless adaptor cap. In response to these disconnections, pharmacy was asked to ensure the tubing collar was tightly attached to the CSTD and similarly, nurses were asked to check the connection prior to administration. Patients receiving infusions greater than 12 hours were particularly vulnerable to infusion disconnection. To address this concern for all hazardous drugs infusions greater than 12 hours, the CSTD was connected directly to the central line lumen, rather than the needleless adaptor cap. Nursing commented that the CSTD syringe adaptor was unable to be easily disinfected, due to the internal space of the adaptor (Figure 2) and that the CSTD Luer lock was incompatible with the disinfection cap used on the needleless adaptors commonly used in the hospital. This proved to be troublesome if a patient needed to be temporarily disconnected and subsequently reconnected to a hazardous drugs infusion, because nurses were unable to disinfect the syringe adaptor. To avoid contamination nurses were instructed to cover the disconnected adapter with a cap from an unopened syringe adaptor package. All mitigation steps were fully implemented prior to January 2017.

CLABSI rates decreased in the post-implementation period after mitigation steps were initiated [49 CLABSI/31,043 CL-days; rate = 1.6/1000 CL days; P=0.004 vs. implementation]. There was no difference in CLABSI rate between the pre-implementation and post-implementation period (P=0.120).

Discussion

In this study, we found an association between the introduction of a new CSTD in our oncology wards and an increase in the CLABSI rate. The CLABSI rate during the implementation period was significantly higher than both the pre- and post-implementation periods. We found no other published studies correlating an increase in CLABSI rates with a CSTD. However, our findings are consistent with other reports of an increase in CLABSI incidence after the implementation of a new vascular device [4–7]. Field *et al*. reported an increase in CLABSI after the introduction of a needless mechanical valve connector in a haematology-oncology ward [5]. Another study found the rate of CLABSI increased from 3.87 to 10.64 infections per 1000 central line days after the implementation of a positive-displacement connector valve [4].

Although we are unable to establish a clear causal relationship between the increase in CLABSI and the CSTD device, there is evidence of an association. We identified several possible explanations for the CLABSI increase; the new CSTD was incompatible with current intravenous administration tubing, required additional device manipulation, and was prone to unexpectedly disconnecting. When mitigation interventions were implemented to correct the issues identified with the device the CLABSI rate decreased to the pre-implementation period level. These factors are a possible reason our facility experienced an increase in CLABSI rates whereas other healthcare facilities without these concerns experienced no negative impact after the implementation of a CSTD.

The CLABSI rate for the six oncology wards has remained consistent with a rate of 1.68 since the end of the post

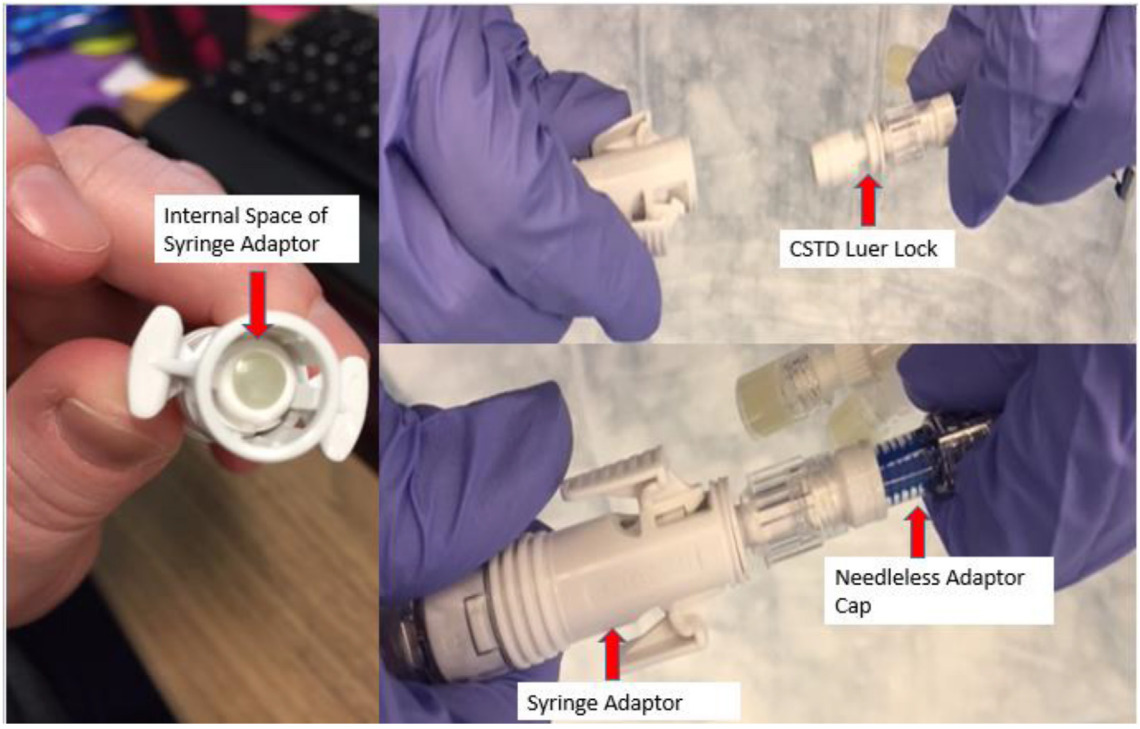

Figure 2. CSTD Syringe adaptor, CSTD Luer lock and needleless adaptor cap used on the six oncology Wards.

implementation period through November 2022. However, we are unable to ascertain if the CLABSI rate is due to the mitigation efforts introduced for the CSTD or other CLABSI reduction efforts instigated at our facility. Since 2018, our facility has implemented several CLABSI reduction interventions, including chlorhexidine gluconate (CHG) bathing, CHG transparent central line dressings, and dedicated central line dressing auditors. In addition to the changes at our facility, there have been updates to the NHSN blood stream infection event definition, which may have affected the rates.

This study was limited to a single academic medical center; therefore, results may not extrapolate to other settings. Additional studies are needed to fully assess the impact of CSTDs on CLABSI rates.

In conclusion, the introduction of a new CSTD incompatible with currently used intravenous administration tubing was associated with a temporary significant increase in CLABSI rates. IP was not included in the review or selection of the CSTD implemented at our facility. This oversight led to the use of an incompatible intravascular device. Our findings highlight the importance of including multiple perspectives when evaluating and implementing a new medical device. It is essential to consider the patient safety impact of all new devices to prevent unintended consequences or patient harm.

Conflict of interest

None declared.

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Ethics

The study did not require ethical approval. The facility institutional review board (IRB) determined since the study did not use identifiable data or specimens it fell outside the purview of the human research protection office.

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