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To link to this article: https://doi.org/10.1016/j.jegh.2017.10.008

Published online: 16 April 2019

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A R T I C L E   I N F O
Article history:
Received 16 June 2017
Received in revised form 23 September 2017
Accepted 24 October 2017
Available online 28 October 2017

Keywords:
Healthcare-associated infection
Infection control
Public health
Central line-associated blood stream infection
Ventilator-associated pneumonia
Catheter-associated urinary tract infection

A B S T R A C T
Healthcare-associated infections (HAIs) including device-associated HAI (DA-HAI) are a serious patient safety issue in hospitals worldwide, affecting 5–10% of hospitalized patients and deadly for patients in intensive care units (ICUs) [1]. An estimated 100,000 patients die every year due to HAIs, at a cost of $17 billion to $29 billion [4,5]. The pooled ICU data shows a catheter-associated urinary tract infections (CAUTI) rate of 3.1–7.5/1000 days, a central line-associated blood stream infections (CLABSI) rate of 3.1–7.5/1000 days, a central line-associated blood stream infections (CLABSI) rate of 3.1–7.5/1000 days, and a ventilator-associated pneumonia (VAP) rate of 2.5–12.3/1000 days [5]. In developing countries, although accurate estimates and information about device-associated HAI (DA-HAI) is scant [2,3], surveillance study conducted by the International Nosocomial Infection Control Consortium (INICC) of 503 ICU beds in countries in Latin America, Asia, Africa, and Europe from 2007 to 2012 showed that DA-HAIS rates were higher in the ICUs of those hospitals. The pooled rate of CLABSI infection is nearly 5-fold higher than the reported CLABSI rates from comparable United States (U.S.) ICUs. The overall rates of VAP and CAUTIs were also higher [6].

Many studies and literature reviews have demonstrated that effective implementation of an integrated infection control program that focuses on DA-HAI surveillance can prevent about...
two-thirds of HAIs. Studies reported that with the implementation of such programs, there can be a reduction in DA-HAI by as much as 30%, along with a reduction in health care costs [7,8]. Surveillance is an essential tool in quality improvements and patient safety that helps to determine the endemic infection rates, which allows for the early detection of epidemics, risk assessment for better future planning, and evaluation of new interventions [9].

Targeted DA-HAI surveillance has been implemented in most hospitals in developed and developing countries, as has benchmarking with the National Healthcare Safety Network (NHSN) database [3].

The INICC system is also used as a benchmark; it consists of DA-HAI data collected from 215 enrolled hospitals from 36 countries, including developing countries [10]. To minimize the occurrence of DA-HAIs in ICUs, the NHSN-recommended infection control measures to be implemented and enforced. Evidence-based approaches include daily device assessments, intervention bundles, reducing risk factors, continuing health education for ICU staff, the establishment of infection control committees, and antimicrobial stewardship programs [11].

Although DA-HAI represents a real public health problem [12], it is still an evolving area of critical care research and continued advancements in this field are foreseen [11]. Also, although previous studies have shown that developing countries have higher DA-HAI rates than the United States and other European countries, the amount of accurate surveillance data remains insufficient [2,3,6].

The Kingdom of Saudi Arabia (KSA), like other developing countries, has limited data regarding DAI rates in general hospitals, and most of the published studies are limited to certain devices [2]. The main aim of this study is to identify DA-HAIs rates in KSA in general hospitals over the timeframe 2013–2016 based on the dataset received from different general hospitals.

Knowing this information is critical and vital for the sake of patient health as well as for the benefit of health authorities in identifying areas or health care settings with high infection rates. With this information, they can take action accordingly and initiate immediate improvement plans. Additionally, studies like this one are an important addition to the published literature and serve as a resource for further research.

2. Methodology

This study is a retrospective cohort study using secondary data from 12 Ministry of Health (MoH) referral hospitals in KSA.

2.1. Study setting

The study took place in adult ICUs of 12 MoH hospitals in different provinces of KSA, with two different ICU types (Cardiac and Medical and Surgical ICU) and differing bed capacities. The surveillance data was completed by trained infection control practitioners in every hospital using a special online INICC multidimensional approach format sent to the MoH Infection Control Department on a monthly basis.

Selected general hospitals implemented the INICC multidimensional approach in their DA-HAI surveillance. The INICC system is focused on the surveillance and prevention of DA-HAI in adult ICUs, pediatric ICUs, and neonatal intensive care units (NICUs).

2.2. INICC multidimensional approach

The INICC implements the methodology of the CDC’s NHSN but adds the collection of other data essential to increasing infection control personnel’s sensitivity to detecting HAIs and avoid under-reporting. The INICC method also includes collecting data from all patients, with and without HAI, and the results of cultures, antibiotic therapy, the average length of stay (LOS), and mortality.

Outcome and process surveillance for this study were conducted by means of an online platform called the INICC Surveillance Online System (ISOS) where information was collected by infection control personnel and uploaded daily to calculate DA-HAI rates per 1000 device days to diagnose CLABSIs, CAUTIs, and VAPs and capture denominator data, patient days, and specific device days in the ICUs. Infection control personnel were trained by the INICC team onsite and also provided with tutorial movies, manuals, and training tools that described in detail how to perform surveillance and upload surveillance data through the ISOS [7].

2.3. Data collection and data source

Data was collected from 12 general governmental hospitals enrolled in the INICC system. The selected hospitals are referral hospitals that are Joint Commission International (JCI) accredited (Table 1).

Data was received from the MoH as a Microsoft Excel™ workbook with personal health identifiers. The data source was de-identified and a unique de-identification key was created in a separate encrypted and locked file for each patient to replace medical record number, date of birth, and bed number. Prior to removing these variables from the initial dataset, age was calculated using the date of birth. Data was received as a separate Excel file for each hospital containing 221 variables, and the data entry fields of the INICC form. The separated files were merged together and all variables were aligned with identical data type, length, and format to create a uniform structured dataset. The de-identified dataset was subsetted and times were transposed to create the variables of interest.

Table 1

<table>
<thead>
<tr>
<th>Group#</th>
<th>Included hospitals</th>
<th>Bed size</th>
<th>Hospital category</th>
<th>Time frame</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Hospital B – Asser Province Hospital E – Qassim Province</td>
<td>&lt;15</td>
<td>All are referral and secondary hospitals</td>
<td>05/15–02/16</td>
</tr>
<tr>
<td>2</td>
<td>Hospital A – Asser Province Hospital F – Taif Province</td>
<td>&gt;15</td>
<td>Both are referral and secondary hospitals</td>
<td>09/13–03/15</td>
</tr>
<tr>
<td>3</td>
<td>Hospital G – Najran Province Hospital H – Tabuk Province</td>
<td>&gt;15</td>
<td>Both are referral and secondary hospitals</td>
<td>09/13–02/16</td>
</tr>
<tr>
<td>4</td>
<td>Hospital I – Taif Province Hospital J – Hail Province Hospital K – Madina Province</td>
<td>&gt;15</td>
<td>All are referral and secondary hospitals</td>
<td>09/15–03/16</td>
</tr>
<tr>
<td>5</td>
<td>Hospital L – Riyadh Province</td>
<td>&gt;15</td>
<td>Referral and secondary hospital</td>
<td>01/15–02/16</td>
</tr>
</tbody>
</table>
The Medical and Surgical ICUs (M/SICUs) under study were categorized into five groups according to the time period of surveillance and number of beds. Data from the Cardiac Care Units (CCUs) was kept separate since this study included only two CCUs and a different time frame.

2.4. Study variables

Given the gradual implementation of the new system, prior to analysis, the datasets were thoroughly examined for inconsistencies, inaccuracies, and invalid entries. During this examination and subsequent data cleaning process, several variables were reclassified or recoded for inaccuracies.

The LOS was calculated as the difference of the discharge/death day from the admission day. For missing admission or discharge dates, the bed days variable that was derived from the system indicating LOS was used. For X hospitals, LOS was offset by 1 day from the bed days variable.

Device days were calculated as the difference of the device end date from the start date. Incorrect device dates that resulted in a negative number of device days, or device days that exceeded the ICU length of stay, or device days that fell outside the admission and discharge time frame were corrected either by recoding an incorrect date to a more likely accurate date relative to other data points (e.g. admission/discharge dates, antibiotic dates, other device dates, culture dates) or setting the device end date(s) to admission and/or discharge date(s). The infection numbers were calculated for every device as the count of the number of infections per device in every hospital for every time period.

2.5. Statistical analysis

Exploratory analysis of data was done and summary statistics for all independent variables were derived. Continuous variables were summarized with descriptive statistics (N, mean, standard deviation, and ninety-five percent confidence intervals). Categorical variables were summarized with frequency counts, proportions and percentages within each category or between levels of a category as appropriate.

DA-HAI rates per 1000 device days were calculated using NHSN criteria for every device (central line, urinary catheter and mechanical ventilator) by dividing the device infection number by the number of device days and multiplying the result by 1000.

Device Utilization Ratio (DUR) was calculated by dividing the number of the device days by the number of bed days. [13–15] These calculations were performed separately for different types of ICUs.

For every device rate, the Standardized Infection Ratio (SIR) was calculated to compare the actual number of HAIs reported in the hospitals included in this study with the baseline U.S. experience (i.e. NHSN aggregate data were used as the standard population). An SIR greater than 1.0 indicates that more HAIs were observed than predicted and less than 1.0 indicates that fewer HAIs were observed than predicted. Adjustments for several risk factors were made that have been found to be significantly associated with differences in infection incidence (e.g. type of the hospitals, bed size and same duration) [16]. The SIR is calculated by dividing the number of observed infections by the number of expected infections. The location's number of device days was multiplied by the NHSN number of observed infections by the number of expected infections. Then, the expected number of device infections for each location was calculated and divided by 1000 to calculate the expected number of infections per 1000 devices. Finally, the hospital's location-specific rates of this study were compared with the NHSN report (2013) [17]. DA-HAI rates and DUR of this study were examined and interpreted with NHSN /INICC percentile reports to determine if the hospital rates or ratio of this study were above or below the 50th percentile (median). It is important to remember that DA-HAI and DUR should be examined together for preventive measure plans to be targeted correctly.

2.6. Ethical considerations

This study did not require IRB review because it did not meet the definition of “human subjects research” or “clinical investigation” as set forth in Emory policies and procedures and federal rules (IRB00087850).

3. Results

In this study, a total of 6178 patients were admitted into the ICUs of the 12 selected hospitals from 2013 to 2016. Of these, 70.7% were female. Women were an average of 44.6 years old and men 52 years old. The average LOS was 10.7 days (0 minimum and 379 day maximum stay). Among the patients studied, the mortality rate was 21.3%.

During the study period of 2013–2016, there were a total of 13,492 DA-HAIs in the 12 MoH hospitals under study. VAP was the most common (57.4%), followed by CAUTI (28.4%), then CLABSI (14.2%). The DA-HAI mortality rates were 41.9% for CLABSI, 40.5% for VAP, and 36.9% for CAUTI (DA-HAI rates in this study have been standardized with the NHSN rates for accurate comparisons to NHSN data.)

Among ICU patients, the central line had an average of 7.9 device days, the mechanical ventilator had 7.8 days, and the urinary catheter had 7.6 days. The DA-HAI results were organized by the type of ICU and the group of the hospitals that are gathered by time frame mentioned that will be decelerated later.

3.1. DA-HAIs in cardiac care units (CCUs) of two hospitals

3.1.1. CLABSI

CLABSI rates were zero per 1000 device-days in both CCUs in Hospital A and Hospital B, although the latter had less than 50 device days which potentially affected the accurate estimation of the rate since the denominator is small (Table 2) [17]. The CLABSI rates of zero in the MoH CCUs under study were less than the mean for U.S. hospitals (1.1) and are comparable to the NHSN's 10th percentile.

The central line utilization ratio in Hospital A was 0.46 (95% CI 0.38–0.56), at the 50th percentile of NHSN. In Hospital B, the ratio was 0.74 (95% CI 0.5–1.05), which is above the 90th percentile of the NHSN utilization ratio (less than the 75th percentile of INICC ratio (Table 3).

3.1.2. CAUTI

Hospital A's rate was 1 per 1000 device-days (95% CI 0.21–3.34) while Hospital B's was 2.6 (95% CI 0.23–11.77) (Table 2). These are at the 50th percentile of NHSN and not far from the mean of U.S. hospitals (2.2). The urinary catheter utilization ratio in both CCUs was above the 90th percentile of the NHSN utilization ratio (and under the 75th percentile of the INICC ratio).
3.3.3. VAP

The VAP rate in Hospital A was very high: 8.1 per 1000 device-days (95% CI: 0.74–37.90) (Table 2). This rate was way above the 90th percentile of NHSN data (but near the 50th percentile of INICC data). In contrast, Hospital B had a rate of zero per 1000 device-days.

The mechanical ventilator utilization ratio in both CCUs was above the 90th percentile of NHSN’s utilization ratio (as well as INICC’s). The utilization ratio was 0.53 (95% CI 0.44–0.63) in Hospital A and 0.55 (95% CI 0.43–0.68) in Hospital B.

3.2. DA-HAIs in Medical/Surgical ICUs (M/SICUs) of 12 hospitals

3.2.1. CLABSI

In Group 1 (four hospitals with under 15 beds over a 9 month period) the CLABSI rate ranged from 0 to 6.19/1000 device-days. These rates are comparable with the 50th percentile of NHSN data (Table 2).

In Group 2 (two hospitals with over 15 beds and over a 17 month period), the CLABSI rate ranged from 0 to 4.28/1000 device-days. The rate of zero is at NHSN’s 25th percentile. The upper range (4.28) is comparable to the INICC pooled mean (Table 2).

In Group 3 (two hospitals with over 15 beds over a 29 month period), the CLABSI rate ranged from 6.68 to 10.89/1000 device-days. This range is over the 90th percentile of NHSN (and at the 75th percentile of INICC data) (Table 2).

In Group 4 (three hospitals with over 15 beds over a 6 month period), the CLABSI rates ranged from 0 to 22.8/1000 device-days. Two of the three hospitals fell within the 50th percentile of NHSN data, and the other was an outlier, higher than the 90th percentile of NHSN (and INICC) (Table 2).

In Group 5 (one hospital with over 15 beds over a 14 month period), the CLABSI rate was 10.2 per 1000 device-days (95% CI; 0.459–54.25), which is over the 90th percentile of NHSN (and under the 75th percentile of INICC data) (Table 2).

Groups 1, 3 and 4 had high central line utilization ratios compared to the NHSN utilization ratio; they exceeded the 90th percentile. In contrast, Groups 2 and 5 had low central line utilization ratios. Group 2’s was 0.33 (95% CI 0.31–0.34) and Group 5’s was 0.05 (95% CI; 0.68–0.06), both below the 10th percentile of the NHSN ratio (Table 3).

3.2.2. CAUTI

As seen in Table 2, the CAUTI rate in Group 1 ranged from 2.3 to 7.19 per 1000 device-days. Two hospitals were at the 75th percentile of NHSN (and under the 50th percentile of INICC). Two hospitals were higher than the 90th percentile of NHSN (and lower than the 75th percentile and the pooled mean of INICC data).

Group 2’s range was 0 to 3.9, Group 3’s range was 1.9–3.5, and Group 4’s range was 0–5.2. Four hospitals had CAUTI rates under NHSN’s 50th percentile and the other three had rates over NHSN’s 75th percentile (but comparable to or less than the INICC pooled mean). Group 5 had a CAUTI rate of 11.75 per 1000 device-days (95% CI; 4.46–25.75), which is higher than the 90th percentile of NHSN (and higher than the 75th percentile of INICC).

Urinary catheter utilization ratios in Groups 1, 3, and 4 were higher than other groups. Group 1’s was 0.79 (95% CI; 0.73–0.77), Group 2’s was 0.79 (95% CI; 0.78–0.81), and Group 4’s was 0.85 (95% CI; 0.83–0.88). All of them exceeded the NHSN’s 90th percentile for utilization ratio. On the lower end, Group 2’s ratio was 0.42 (95% CI; 0.40–0.43) and Group 5’s was 0.06 (95% CI; 0.05–0.06), which were less than the 10th percentile of NHSN data (Table 3).

3.2.3. VAP

VAP rates were found to be high in in all M/SICUs (Table 2). In Group 1, they ranged from 18.1 to 26.6 per 1000 device days. In Group 2, they ranged from 9.33 to 20.7 per 1000 device days. In Group 3, they ranged from 0.9 to 16.4 per 1000 device days, and in Group 4, they ranged from 10.1 to 51.6 per 1000 device days (one hospital from this group was not included in this range because its number of device days was less than 50, which can affect the reliability of the estimate) [17]. VAP rates in most of the hospitals were much higher than the NHSN mean (but within the INICC mean). Group 5 had an outlier VAP rate of 186.5 per 1000 device days (95% CI; 111.44–275.04). All VAP rates in the hospitals under study exceeded the 90th percentile of the NHSN (and were between the 75th and 90th percentile of INICC data) except for one in Group 3 (Table 2).

The mechanical ventilator utilization ratio in Group 1 was 0.54 (95% CI; 0.52–0.56), in Group 3 it was 0.65 (95% CI; 0.64–0.66), and in Group 4 it was 0.94 (95% CI; 0.90–0.98) (Table 3). These were all high utilization ratios that exceeded the 90th percentile of NHSN’s utilization ratio (Groups 1 and 3 were at the 75th percentile of INICC’s ratio and Group 4 was at the 90th). Group 2 had a lower mechanical ventilator utilization ratio: 0.31 (95% CI; 0.29–0.32), at the 50th percentile of the NHSN. Group 5 had the lowest device utilization ratio among the groups, 0.05 (95% CI; 0.04–0.06), which was under the 10th percentile of NHSN’s ratio (Table 3).

4. Discussion

The results showed that during the study period from 2013 to 2016, VAP was the most common DA-HAI (57.4%) in the hospitals included in this study, followed by CAUTI (28.4%) then CLABSI.
Table 3

<table>
<thead>
<tr>
<th>Hospital</th>
<th>ICU</th>
<th>Central line utilization ratio (95% CI)</th>
<th>Urinary catheter utilization ratio (95% CI)</th>
<th>MV-ventilator-device utilization ratio (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Group 1 (4 hospitals)</td>
<td>Medical/Surgical BED &lt; 15</td>
<td>0.69 (0.64–0.74)</td>
<td>0.75 (0.70–0.80)</td>
<td>0.71 (0.65–0.77)</td>
</tr>
<tr>
<td>Group 2 (2 hospitals)</td>
<td>Medical/Surgical BED &gt; 15 (09/09–15/10)</td>
<td>0.55 (0.50–0.60)</td>
<td>0.62 (0.57–0.67)</td>
<td>0.61 (0.55–0.67)</td>
</tr>
<tr>
<td>Group 3 (2 hospitals)</td>
<td>Medical/Surgical BED &gt; 15 (09/09–13/02)</td>
<td>0.58 (0.53–0.63)</td>
<td>0.56 (0.50–0.61)</td>
<td>0.55 (0.50–0.60)</td>
</tr>
<tr>
<td>Group 4 (3 hospitals)</td>
<td>Medical/Surgical BED &gt; 15 (09/09–15/08)</td>
<td>0.50 (0.45–0.55)</td>
<td>0.51 (0.46–0.56)</td>
<td>0.50 (0.45–0.55)</td>
</tr>
<tr>
<td>Group 5 (1 hospital)</td>
<td>Medical/Surgical BED &gt; 15 (09/09–13/02)</td>
<td>0.50 (0.45–0.55)</td>
<td>0.51 (0.46–0.56)</td>
<td>0.50 (0.45–0.55)</td>
</tr>
</tbody>
</table>

In the two CCUs in our study, the CLABSI rates were lower than the NHSN benchmark, with a high central line utilization ratio. CAUTI rates were at the 50th percentile of NHSN and similar to the mean of U.S. hospitals, with a very high urinary catheter utilization ratio. The VAP rate in Hospital A’s CCU was 8.1 per 1000 device days, and zero in Hospital B’s CCU. Hospital A’s high infection rate only reflects the presence of a single case. Between the two CCUs, the timeframes measured were distinct: Hospital A’s surveillance took place over 17 months, and Hospital B’s took place over 9 months. Both hospitals had high MV utilization ratios (over the NHSN’s 90th percentile); still, Hospital B had zero infections.

In most of the 12 M/S ICUs in our study, we found very good CLABSI rates. These were at the 50th percentile of NHSN benchmarks. Notable CLABSI rates in individual hospitals were as follows: Hospitals A, B, C, E and I had CLABSI rates of zero per 1000 device-days. Hospital J, in Hail, had the greatest CLABSI rate: 22.8 per 1000 device-days (95% CI: 12.1–39.47), which was an outlier in the hospitals under study. All but two of the M/S ICUs had high central line utilization ratios (over the NHSN’s 75th percentile).

CAUTI rates in three of the 12 hospitals (A, K and I) were less than the NHSN pooled mean and four (B, C, D, F) had rates lower than the 50th percentile of INICC benchmarks. The urinary catheter utilization ratio in most of these M/S ICUs exceeded the 90th percentile of the NHSN’s utilization ratio [6,17].

VAP rates in most of the M/S ICUs in the hospitals under study were much higher than the NHSN mean but near the INICC mean and within its confidence interval, with very high mechanical ventilator utilization ratios.

A cohort study conducted from 2008 to 2010 in China demonstrated a nearly similar result: VAP (10.46/1000 device days) was the predominant DAI followed by CLABSI (7.66/1000 device days), then CAUTI (1.29/1000 device days) [3].

The overall DAI rates were much higher than those in the U.S. and even higher than previous studies in KSA had shown (among various health sectors). The variations in DAI rates among the studies cited could be related to the distinct protocols in place in different health sectors (i.e., MoH, National Guard, ARAMCO, military) and the different application of preventive measures (e.g., bundles) by hospital [2,7,18–23].

The hospitals in this study met some but not the majority of NHSN benchmarks for DA-HAIs. Most did however fall into the 50th percentile or lower of INICC data, which includes data from different developing countries. In benchmarking to the NHSN data, researchers should take into consideration the differences in surveillance environments and NHSN hospitals, which may have stricter protocols, continuous monitoring, and immediate interventions, which are still challenges in KSA hospital settings.

This study had a few limitations. First, the accuracy of our surveillance data could have been affected by the lack of compliance of the healthcare workers to the new electronic INICC system versus the old paper-based system. Despite the implementation of INICC training programs, it takes time for new knowledge and skills to translate into accurate reports [10]. For example, an
inconsistent method of computing the dates in the INICC system was found that led to incorrect device and bed days that this study manually corrected.

Second, calculating the rates of DA-HAIs per 1000 device-days was difficult due to the variable surveillance period durations among the participating hospitals.

Third, no records or data found for the outbreaks that are specific for device associated nosocomial infections in our hospitals which can explain why some DA-HAIs are very high in some hospitals. Our national outbreak surveillance system is not well established and still under construction.

Finally, some hospital data was not provided. There are more than 12 participating INICC hospitals, but some hospitals didn't send their monthly surveillance data to the MoH.

5. Conclusion and recommendations

This study found that KSA still faces certain challenges in infection control such as lack of compliance with the electronic surveillance system, a high rate of DA-HAI, and high DUR, especially in ICUs.

Higher device-associated infection rates and higher DUR in the study's CCUs and M/SICUs were found compared to National Healthcare Safety Network (NHSN) benchmarks, except for CLABSI rates, which were lower. To improve patient care and decrease infection rates in KSA ICUs, ongoing monitoring of infection control practices and comprehensive education are required. Furthermore, a sensitive and specific national healthcare safety network is needed in KSA and more published studies are needed on HAI rates that can serve as resources and references for future studies.

References


