

The effect of process control on the incidence of central venous catheter-associated bloodstream infections and mortality in intensive care units in Mexico*

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Purpose: To ascertain the effect of an infection control program including process control on intensive care unit (ICU) rates of intravascular device (IVD)-associated bloodstream infection (BSI).

Setting: Two level III adult ICUs in one public university hospital in Mexico: one medical surgical ICU and one neurosurgical ICU.

Population Study: All adult patients admitted to study units who had a central venous catheter (CVC) in place for at least 24 hrs.

Methods: A prospective before/after trial in which rates of IVD-associated BSI are determined during a period of active surveillance without process control (phase 1) were compared with rates of IVD-associated BSI after implementing an infection control program applying process control (phase 2).

Results: Six hundred five IVD-days were accumulated in phase 1, and 2824 IVD-days were accumulated during phase 2. Compliance with CVC site care and hand hygiene improved significantly from baseline during the study period: placing a gauze dressing over the catheter insertion site (99.24% vs. 86.69%, respectively; relative risk [RR] = 1.14; 95% confidence interval [CI] = 1.07–1.22; $p = .0000$), proper use of gauze for vascular catheter

insertion site (97.87% vs. 84.21%, respectively; RR = 1.16; 95% CI = 1.09–1.24; $p = .0000$), documentation of the duration of the administration set of the vascular catheter (93.85% vs. 40.69%, respectively; RR = 2.34; 95% CI = 2.14–2.56; $p = .0000$), and hand hygiene before contact with the patient (84.9% vs. 62%, respectively; RR = 1.37; 95% CI = 1.21–1.51; $p = .0000$). Overall rates of IVD-associated BSI were lowered significantly from baseline rates after implementation of process control (19.5 vs. 46.3 BSIs per 1000 IVD-days, respectively; RR = 0.42; 95% CI = 0.27–0.66; $p = .0001$). Overall rates of crude unadjusted mortality were lowered significantly from baseline rates (48.5% vs. 32.8% per 100 discharges, respectively; RR = 0.68; 95% CI = 0.50–0.91; $p = .01$).

Conclusion: Implementation of an infection control program utilizing education, process control, and performance feedback was associated with significant reductions in rates of IVD-associated BSI and mortality. (Crit Care Med 2005; 33:2022–2027)

KEY WORDS: bacteremia; bloodstream infection; catheter-related bloodstream infection; central catheter-associated bloodstream infection; central venous catheter; vascular catheter; nosocomial infection; hospital infection; infection control program; process control; Mexico; developing country; intensive care unit; adults

Hospitalized critically ill patients have a significant risk of developing nosocomial infections. Most nosocomial bloodstream infections (BSIs) are primary, mainly originating in intravascular devices (IVDs) (1–4). IVD-associated BSIs

significantly increase attributable mortality (5, 6), the length of hospitalization, and the cost of health care (5, 7, 8).

Infection control programs in Latin America are not mandatory in many countries. This lack of governmental oversight has resulted in a low awareness of the need for infection control programs. As a result, the rates of IVD-associated BSIs are higher than in industrialized countries (9). As part of an international project led by one of us (VDR) to determine the prevalence of device-associated infections in different countries, we previously reported high rates of device-associated nosocomial infection in countries of Latin America and Europe (10–16). In particular, rates of IVD-associated BSI were exceeded by three to five times the 50th percentile of

National Nosocomial Infection Surveillance (NNIS) System rates.

We report the results of a prospective, before/after trial that assessed the effectiveness of implementing an infection control program utilizing process control for reducing the rates of IVD-associated BSI among patients from two level III neurosurgical and medical surgical intensive care units (ICUs) in one Mexican public hospital.

METHODS

Setting. The study is part of an international multicenter project of nosocomial infection surveillance and infection control called the International Infection Control Consortium led by one of us (VDR). The project has been using Center for Diseases Control and Prevention definitions of nosocomial infections (17) and NNIS System meth-

*See also p. 2133.

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odology for surveillance of device-associated nosocomial infections (18) and currently includes 49 ICUs of 39 hospitals in 28 cities of 12 countries from Latin America, Asia, Africa, and Europe.

The present study was conducted in one public 1,000-bed hospital in Mexico, which has six ICUs. We conducted the study at the medical surgical ICU (12 beds) and the neurosurgical ICU (12 beds). There were six nurses per ICU per work shift during the entire study. The selected ICUs in the study center care for patients who have undergone neurosurgical, general, and orthopedic surgery as well as patients with severe medical illness. The institutional review board at the center approved the study protocol.

Data Collection. During the entire study period (June 2002 to May 2003), all patients with a central venous catheter (CVC) for >24 hrs who were admitted to the study ICUs were enrolled. A medical doctor at each study ICU extracted patient data prospectively from charts. The founder and coordinator of the International Infection Control Consortium (VDR) trained the data collectors at each ICU before initiation of the trial. The patient's age, sex, duration of catheterization, antibiotic use, use of other invasive devices, and other sites of infection while catheterized were recorded for each study patient. Study center data collection sheets were checked for potential errors and missing items by the project coordinator to confirm each diagnosis of IVD-associated BSI. We collected data prospectively on both types of BSI: laboratory-confirmed BSI and clinical sepsis.

Usual Catheter Care Practices. CVCs are inserted using cutaneous antiseptics with povidone-iodine. Full barrier precautions are used occasionally as resources permit. If a dressing is used at all, it is a gauze dressing; no transparent dressings are used. We use a semirigid plastic open infusion system with an air filter instead of a collapsible flexible closed infusion system (19).

Definitions. We used NNIS System criteria to define the diagnosis of BSI as follows (20): laboratory-confirmed BSI—criterion 1, patient had a recognized pathogen cultured from one or more percutaneous blood specimens after 48 hrs of vascular catheterization, and the pathogen isolated from the blood was not related to an infection at another site; for common skin commensals (e.g., diphtheroids, *Bacillus* species, *Propionibacterium* species, coagulase-negative staphylococci, or micrococci), the organism was cultured from two or more blood specimens obtained on separate occasions; criterion 2, patient had fever (temperature, >100.4°F [$>38^{\circ}\text{C}$]), chills, and/or hypotension that was not considered to be related to an infection at another site; clinical primary nosocomial sepsis—patient had fever (temperature, >100.4°F [$>38^{\circ}\text{C}$]), hypotension (systolic blood pressure, <90 mm Hg), and/or oliguria (<20 mL/hr) with no other recognized cause, but blood specimens were

not obtained for culture or organisms were not recovered from blood cultures; however, there was not apparent infection at another site, and the physician instituted treatment for sepsis (21).

Culture Techniques. Decisions to remove catheters and obtain blood specimens for culture were made independently by the patient's attending physicians. CVCs were removed aseptically, and the last 5 cm of the catheter tip was cultured using a semiquantitative method (22). All cultures were inoculated within 8 hrs of catheter removal. For purpose of blood culture, two blood samples (5–10 mL) were obtained from two separate veins within an interval of 15–20 mins, inoculated in a 50-mL bottle, and sent to the microbiological laboratory. Standard laboratory methods were used to identify microorganisms colonizing the CVC tips.

Periods. We divided the study in two periods. The baseline period (phase 1) was between June and August 2002 (3 months). The period of the multifaceted intervention was phase 2, which was started in September 2002 and continued throughout May 2003 (9 months).

Process Control. Hand hygiene compliance and catheter care compliance were assessed and incorporated in a standardized form. Placement of gauze on IVD insertion sites, marking the date on the intravenous administration set, condition of the gauze dressing, and hand hygiene with alcohol hand rub or povidone-iodine soap before patient contact were assessed and entered into a standard form by local researchers who observed healthcare worker behaviors in the study units 5 days a week. The gauze dressing was inspected, and the presence or absence of moisture, blood, and gross soilage and the appearance of the insertion site were noted.

Intervention. Active surveillance for IVD-associated infections and compliance with IVD site care and hand hygiene were begun with phase 1 and continued through phase 2 (18). The intervention period was a multifaceted time during which education, observation, process control, and performance feedback of hand hygiene and catheter care occurred. The education process was led by an infection control nurse who presented a number of classes, including epidemiology of nosocomial infections, hand hygiene, disinfection, prevention of vascular catheter-associated BSIs, prevention of ventilator-associated pneumonia, and prevention of urinary catheter-associated urinary tract infections. Each class lasted for 1 hr and was given to all the work shifts. During the study period, very few new nurses started work in the ICU; for this new staff, the infection control nurse provided extra classes. During 2003, new medical residents started their training period; for this group, the infection control nurse provided extra classes.

The performance feedback consisted of a chart with columns representing each month showing hand hygiene and invasive device care. The charts were posted on the walls of

the ICU on a monthly basis, in a visible place in front of the healthcare workers (nurses, ancillary staff, and physicians). The infection control guidelines used were the infection control practices published by Centers for Disease Control and Prevention/HICPAC (9, 23, 24). We started to use alcohol hand rub or hand washing with povidone-iodine soap during the intervention period. Previously, we were using regular non-antiseptic soap. Performance feedback of catheter care and hand hygiene was provided on a monthly basis in the form of bar charts documenting rates of compliance with hand hygiene, gauze on CVC insertion sites, dates on intravenous administration sets, and maintenance of gauze dressings on catheter sites.

Outcomes. The primary outcome was the rate of IVD-associated BSI in phase 2 vs. phase 1. Secondary outcomes were hand hygiene, catheter care compliance, and mortality rate in phase 2 compared with phase 1.

Statistical Methods. EpiInfo version 6.04b was used for data analysis. Baseline differences between treatment groups were analyzed using chi-square analyses for dichotomous variables and Student's *t*-test for continuous variables. When appropriate, Fisher's exact probability test was used. Relative risk (RR) ratios, 95% confidence intervals (CI), and *p* values were determined for all primary and secondary outcomes.

RESULTS

During the study period, 470 adult patients in the study ICUs required CVCs, and all of these patients were enrolled in the study. Patients from phase 1 were very similar to patients from phase 2 with regard to sex, age, diabetes mellitus, cardiac failure, chronic obstructive pulmonary disease, smoking, alcoholism, and renal impairment (Table 1). During phase 1 in the medical surgical ICU, we enrolled 74 patients, and during phase 2, we enrolled 148 patients. During phase 1 in the neurosurgical ICU, we enrolled 99 patients, and during phase 2, we enrolled 149 patients (Table 2). The percent occupancy (45.9% in phase 1 and 40.1% in phase 2; RR = 0.84; 95% CI = 0.69–1.02; *p* = .08) and nurse-to-patient ratios (0.54 in phase 1 and 0.61 in phase 2; RR = 1.0; 95% CI = 0.91–1.10; *p* = 1.0) were not significantly different (Table 3).

Six hundred five CVC-days were accumulated in phase 1 (June, July, and August 2002), and 2824 IVD-days were accumulated during phase 2 (September 2002 to May 2003). Overall rates of CVC-associated BSI were lowered significantly from baseline rates after the implementation of education, process control, and performance feedback (19.5 vs. 46.3 BSIs

per 1000 IVD-days, respectively; RR = 0.42; 95% CI = 0.27–0.66; $p = .0001$) (Table 4). We found a reduction in IVD-associated BSI rates in both units. In the medical surgical ICU, the reduction was statistically significant (22.1 vs. 57.4, respectively; RR = 0.38; 95% CI = 0.22–0.68; $p = .000$). In the neurosurgical ICU, the reduction failed to reach statistical significance (17.1 vs. 32.8, respectively;

RR = 0.52; 95% CI = 0.24–1.11; $p = .08$). The time sequence of BSI rates is shown in Figures 1 and 2. One hundred thirty-two patients were discharged in phase 1, and 338 were discharged during phase 2. Overall rates of crude unadjusted mortality were lowered significantly from baseline rates (32.8% vs. 48.5% per 100 discharges, respectively; RR = 0.68; 95% CI = 0.50–0.79; $p = .01$) (Table 4).

During the study periods, we evaluated compliance with proper catheter care for a total of 1413 observations in phase 1 and 2912 observations in phase 2. Compliance with placing a gauze dressing over the catheter insertion site improved significantly with education, process control, and performance feedback (99.24% vs. 86.69%, respectively; RR = 1.14; 95% CI = 1.07–1.22; $p = .0000$) (Table 5). Compliance with proper use of gauze at the vascular catheter insertion site improved significantly with education, process control, and performance feedback (97.87% vs. 84.21%, respectively; RR = 1.16; 95% CI = 1.09–1.24; $p = .0000$) (Table 5). Compliance with documenting the duration of the administration set of a vascular catheter improved significantly with education, process control, and performance feedback (93.85% vs. 40.69%, respectively; RR = 2.34; 95% CI = 2.14–2.56; $p = .0000$) (Table 5). Five hundred eighty-four hand washing opportunities were observed in phase 1 (June, July, and August 2002), and 1,122 were observed during phase 2 (September 2002 to May 2003). Compliance with hand hygiene before contact with the patient improved significantly with education, process control, and performance feedback (84.9% vs. 62%, respectively; RR = 1.37; 95% CI = 1.21–1.51; $p = .0000$) (Table 5).

DISCUSSION

CVCs are indispensable to the care of the critically ill patient. However, their use is associated with significant complications, the most important of which is BSI (25, 26). Catheter-associated BSIs increase the length of hospitalization (8) and are associated with excess costs (5, 7, 8) and, in some studies, an attributable mortality rate of 12% to 25% (5, 6). Studies from Latin America showed that nosocomial infections increase the length of hospitalization and the attributable mortality rate (11). A prior study from Argentina analyzing adjusted attributable length of stay, cost, and mortality rate found a prolongation of hospital stay of 12 days, an excess cost of \$4888, and an attributable mortality rate of 25% (27). We found high baseline rates of IVD-associated BSIs of 46.3 cases per 1000 CVC-days. Data from US ICUs collected by the NNIS System showed rates of 4.0 cases per 1000 CVC-days in teaching medical surgical ICUs and 4.6 cases per 1000 CVC-days in neurosurgical ICUs

Table 1. Baseline characteristics of patients at study entry

Characteristic	Phase 1 (n = 132)	Phase 2 (n = 338)	<i>p</i>
Males	60 (45.5)	163 (48.2)	.588
Mean age (yr) ± SD	44.32 ± 18.3	45.91 ± 17.88	.422
Diabetes	26 (19.7)	72 (21.3)	.700
Cancer	1 (0.8)	7 (2.1)	.322
Hypertension ^a	22 (16.7)	75 (22.2)	.183
Cardiac failure	3 (2.3)	16 (4.7)	.223
COPD	3 (2.3)	16 (4.7)	.223
Smoker	17 (12.9)	55 (16.3)	.358
Alcoholism	24 (18.2)	65 (19.2)	.794
Renal impairment	3 (2.3)	19 (5.6)	.722

COPD, chronic obstructive pulmonary disease.

^aSystolic blood pressure of >140 mm Hg; unless indicated otherwise, data are no. (%) of patients.

Table 2. Distribution of patients by unit and by month

Month	Medical Surgical ICU Patients	Neurosurgical ICU Patients	Overall ICU Patients
June 2002	13.0	30.0	43
July 2002	16.0	26.0	42
August 2002	23.0	24.0	47
Total phase 1	52	80	132
Monthly average phase 1	17.3	26.6	44
September 2002	22.0	19.0	41
October 2002	23.0	19.0	42
November 2002	18.0	20.0	38
December 2002	16.0	23.0	39
January 2003	18.0	21.0	39
February 2003	23.0	22.0	45
March 2003	21.0	15.0	36
April 2003	15.0	10.0	25
May 2003	14.0	19.0	33
Total phase 2	170	168	338
Monthly average phase 2	18.8	18.6	37.6
Total phases 1 and 2	222	248	470
Total monthly average	18.5	20.6	39.1

ICU, intensive care unit.

Table 3. Percent occupancy and nurse-to-patient ratio in the study ICUs

Finding	Phase 1	Phase 2	RR	95% CI	<i>p</i>
Total no. of patients	132	338			
Monthly average no. of patients	44.0	37.5			
Total available ICU bed-days	2160	6480			
Actual bed occupancy (%)	45.9	40.1	0.84	0.69–1.02	.08
Total available nurse-days	540	1620			
Nurse-to-patient ratio	0.54	0.61	1.00	0.91–1.00	1.00

ICU, intensive care unit; RR, relative risk; CI, confidence interval.

Table 4. Rates of intravascular device (IVD)-associated bloodstream infection (BSI) and mortality

Finding	Phase 1	Phase 2	RR	95% CI	<i>p</i>
No. of BSIs	28	55			
IVD-days	605	2824			
BSI per 1000 IVD-days	46.3	19.5	0.42	0.27–0.66	.0001
Total patients (n = 470)	132	338			
Total deaths (n = 175)	64	111			
Crude mortality rate (%)	48.5	32.8	0.68	0.50–0.91	.01

RR, relative risk; CI, confidence interval.

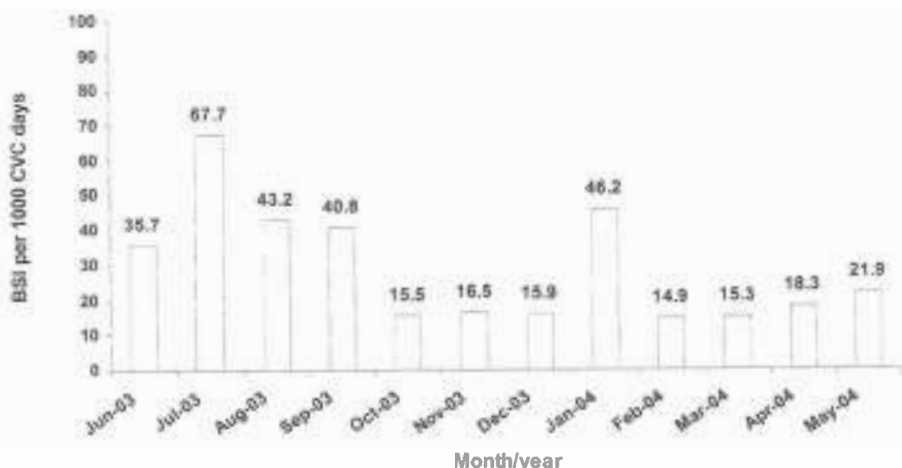


Figure 1. Rate of central venous catheter (CVC)-associated bloodstream infections (BSIs) by month at a medical surgical intensive care unit.

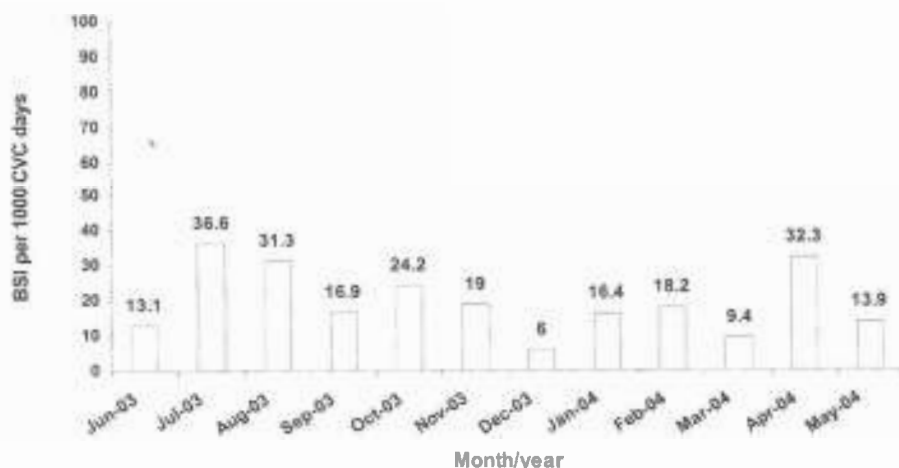


Figure 2. Rate of central venous catheter (CVC)-associated bloodstream infections (BSIs) by month at a neurosurgical intensive care unit.

(28). Because of the lack of national benchmark data in Mexico, we were not able to obtain rates of IVD-associated BSI on a national level. We theorize that our higher rates are a result of a lack of awareness and consistent application of infection control guidelines in the ICUs under study. Limited resources and lack of formal infection control programs and surveillance likely also play a role.

IVD-associated BSIs are largely preventable, and studies have documented the effectiveness of interventions such as education of healthcare personnel regarding catheter insertion and care (29, 30), full barrier precautions with IVD insertion (31), and use of chlorhexidine for skin antisepsis (32) for reducing the rates of IVD-associated BSI. Unfortunately, many healthcare institutions in Latin America lack the resources to implement many of these preventive technologies. Furthermore, some hospitals lack basic infection control programs, and many caregivers are unaware of simple and cost-effective methods for preventing IVD-associated BSI. Education of healthcare personnel represents a simple, cost-effective intervention to decrease rates of IVD-associated BSI and forms the cornerstone of any infection control program. Numerous studies have found that education and training in catheter insertion and subsequent care can result in RR reductions of 50% to 75% (29, 33–35). In our study, we used education, training, process control, and performance feedback of healthcare personnel and found an ≈50% RR reduction with this strategy. We previously showed this to be a successful approach to preventing catheter-associated urinary tract infections and compliance with hand hygiene (36, 37). Berenholtz et al. (38) recently reported their findings of a study using multifaceted interventions to prevent catheter-related BSI in the ICU. They reported a decline in catheter-related BSI rates from 11.3 per 1000 catheter-days to 0 per 1000 catheter-days. They used a more intensive intervention program

Table 5. Compliance with intravascular device (IVD) site care and hand hygiene

Finding	Phase 1	Phase 2	RR	95% CI	<i>p</i>
Presence of gauze on IVD site, %	86.69 (n = 1413)	99.24 (n = 2912)	1.14	1.07–1.22	.0000
Proper placement of gauze at IVD site, %	84.21 (n = 1413)	97.87 (n = 2912)	1.16	1.09–1.24	.0000
Date on IV administration set, %	40.69 (n = 1413)	93.85 (n = 2912)	2.34	2.14–2.56	.0000
Hand hygiene compliance, %	62 (n = 584)	84.9 (n = 1122)	1.37	1.21–1.51	.0000

RR, relative risk; CI, confidence interval; IV, intravascular.

Implementation of an infection control program utilizing education, process control, and performance feedback was associated with significant reductions in rates of intravascular device-associated bloodstream infection and mortality.

than ours, including empowering nurses to stop catheter insertion if the guidelines were being violated and daily assessment of the need for continued catheter placement. Such a labor-intensive approach was not feasible in our study given our limited resources. Nevertheless, we believe that the considerable decline in our rates of catheter-related BSI after implementation of our education and performance feedback protocol serves to highlight the importance of education as a tool for preventing nosocomial infection.

We also found that compliance with proper catheter care including hand hygiene improved considerably after implementing the intervention and that simple measures such as ensuring that the gauze dressing was properly placed and replaced as necessary were performed much more frequently than before the intervention. Compliance with documenting the duration of the administration set and hand hygiene were also considerably improved. In our hospital, we noticed higher hand hygiene compliance than in some other previous studies, and this is because we already had in place a program to improve hand hygiene compliance in the neurosurgical care unit. Our study shows that, particularly in countries with limited resources, education of healthcare personnel may be a very important cost-saving measure that can achieve substantial benefit for prevention of IVD-associated BSI.

Finally, we showed that the crude unadjusted mortality rate decreased significantly in the intervention phase compared with baseline. Because we do not

have data on the cause of death and we did not match patients to detect adjusted attributable mortality, it is not possible to conclude that a reduction in IVD-associated BSI caused the reduction in mortality.

Our study has several limitations. We used the NNIS System definition, which is less than rigorous and may even imprecisely identify patients with just systemic inflammatory response syndrome but without infection as having sepsis. However, we chose to use these widely used and recognized criteria to obtain comparable data with the NNIS System and other countries. Because this was a quasiexperimental study, it is possible that changes in practice beyond what we implemented resulted in lowering of IVD-associated BSI rates. We did not have significant differences in bed occupancy from phase 1 to phase 2, which could create a different nurse-to-patient ratio. It is well known that understaffing is a risk factor for nosocomial infections (39). However, in this study, we did not have understaffing; during the entire study, the nurse-to-patient ratio was ≥ 0.5 , because we have 12 beds per ICU and six nurses per ICU per work shift.

Although we found a substantial benefit with our strategy, the long-term sustainability of such a program remains to be demonstrated, because intensive frequent feedback needed to be provided to healthcare personnel.

CONCLUSION

Through the implementation of this program, including active targeted surveillance for device-associated nosocomial infection using Centers for Disease Control and Prevention definitions, we were found very high BSI and crude unadjusted mortality rates. Through the implementation of Centers for Disease Control and Prevention infection control guidelines and through classes, process control, and performance feedback posted on the wall, we significantly reduced BSI and crude unadjusted mortality rates.

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