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Initial Specimen Diversion Device Utilization Mitigates Blood Culture Contamination Across Regional Community Hospital and Acute Care Facility

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Abstract

A West Virginia regional community hospital incorporated an initial specimen diversion device (ISDD) into conventional blood culture protocol with the objective to bring the hospital-wide blood culture contamination (BCC) rate from a 3.06% preintervention rate to a target performance level below 1%. Emergency department staff, laboratory phlebotomists, and nursing staff on acute-critical care floors were trained on ISDD (Steripath Gen2, Magnolia Medical Technologies, Inc., Seattle, WA) operating procedure and utilized the device for blood culture sample collection with adult patients from September 2020 through April 2021. Of 5642 blood culture sets collected hospital-wide, 4631 were collected with the ISDD, whereas the remaining sets were collected via the conventional method. The ISDD BCC rate of 0.78% differed from the conventional method BCC rate of 4.06% observed during the intervention period (chi-squared test $P < 0.00001$). The ISDD group attained a sub-1% BCC rate to satisfy the intervention objective.

Keywords

Blood culture contamination, antimicrobial stewardship, quality

Introduction

Blood culture, despite longstanding quality control concerns,[1] is the immediate response to suspected bloodstream infection. The incidence of sepsis (6% of adult hospitalizations) and its associated outcomes of death or discharge-to-hospice are stable and substantial, necessitating optimization of the blood culture process.[2] Intervention reducing false-positive blood culture results is presently a more worthwhile pursuit than intervention reducing unnecessary blood culture testing due to the considerable costs associated with blood culture contamination (BCC).[3] Unfortunately, the shortcomings of sample acquisition technique that lead to persistently high BCC rates have been a topic of exhaustive study in quality improvement literature with few contemporary advances that meaningfully impact blood culture result accuracy.[4,5]

At present, blood culture quality control prioritizes reducing human error factors. Educational intervention (often taking the form of performance evaluations, feedback, or regular retraining) is a popular quality control measure and has demonstrated the potential to reduce BCC rates by 35% to 50%[6,7] but will always be susceptible to staff turnover and intentional noncompliance with protocol when staff must prioritize tasks under time constraints imposed by health care environments and emergencies. Patient overcrowding has proven to adversely impact quality of care and is associated with increased BCC rates.[8,9] Indeed, even the *perception* of a heavy workload is correlated with increased BCC,[10] and it is hardly surprising when an emergency department has the highest BCC rate in a given health care system. To encourage strict staff adherence to blood culture protocol in difficult environments, prepackaged sterile kits have been developed to regulate blood culture routine, albeit with inconsistent impact, reducing BCC (9.2% to 3.8%[11]; 10.3% to 4.3%[12]) in some environments, although providing no discernable benefit in others.[13] More reliable than prepackaged kits is the utilization of a dedicated phlebotomy team,[14,15] but the cost can be prohibitive and in many environments such talent is not available. While reducing human error factors is crucial to reducing

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high rates of BCC, eliminating BCC has proven elusive even with strategies that pair dedicated phlebotomists with prepackaged kits and recurring educational intervention. The Clinical and Laboratory Standards Institute presently implies that BCC rates as high as 3% are anticipated and acceptable.[16]

Beyond human error, the primary obstacle to BCC reduction is the draw site and the impossible task of eliminating commensal organisms embedded within the skin.[17] No significant difference exists among contemporary antiseptics (chlorhexidine solutions, isopropyl alcohol, tincture of iodine, and povidone-iodine) regarding their ability to reduce BCC, leaving these topical applications at an impasse in their efficacy.[18,19,20,21] Their ability to eliminate contaminants is chiefly undermined by out-of-reach subsurface skin flora. While blood culture sample acquisition via venipuncture is encouraged over the use of existing intravenous lines due to the risk of these lines harboring contaminants in large quantities,[22,23] piercing the skin to draw blood *will* confine organic debris within the needle lumen.[24] In this way, the sample can be tainted by contaminants that no quality control process conventionally addresses.[25]

The only quality control interventions specifically addressing this problem involve sample diversion. Manually diverting the initial aliquot of a blood sample into a waste tube has gained traction in the literature as a BCC reduction strategy with varying levels of success (30% to 60% BCC reduction) when put into practice.[25,26,27] However, manual diversion limits its own efficacy by introducing additional points of touch contamination to the sample draw process and requiring staff to "juggle" waste tubes amidst the usual stresses of their environment, prompting a recent innovation. Prepackaged sterile, with either an attached needle for venipuncture or Luer lock fitting for connection to a newly placed peripheral intravenous catheter, initial specimen diversion devices (ISDDs) accommodate sterile procedure sample diversion without introducing opportunities for human error into the process, providing a systematized means of quality control and a novel tool for health care facilities seeking to lower BCC rates.

United Hospital Center is a member of the West Virginia University Health System, functioning as a regional community hospital and acute care facility with 292 inpatient rooms in North Central West Virginia. After a previous multifaceted intervention failed to sustain BCC rates below a 3% target rate threshold, ISDD acquisition, and utilization was considered for the emergency department, phlebotomy lab, and acute-critical care floors at United Hospital Center. ISDD implementation outcomes in other health care systems had been promising (80% to 100% BCC reduction), but these studies were limited to either emergency department or inpatient environments and never both simultaneously.[28,29] While efficacy in all environments was uncertain, ISDD utilization was considered unlikely to compromise the sensitivity of blood culture tests[29] and had the potential to be cost-saving due to the small device cost relative to the mean $2100 cost United Hospital Center attributes to contamination events.[30] An ambitious objective was established to bring the hospital-wide BCC rate below a 1% target rate threshold. Such a reduction would provide impacted patients with a higher standard of care by reducing misdiagnoses of blood stream infection (including sepsis), curtailing unnecessary antibiotic therapy and shortening length of stay.

Methods

For the intervention period (September 2020 through April 2021), the ISDD (Steripath Gen2, Magnolia Medical Technologies, Inc., Seattle, WA) was evaluated for its ability to reduce BCC hospital-wide at United Hospital Center in a pragmatic, prospective, controlled, and nonrandomized study. The ISDD (a sterile, vein-to-bottle closed-system) integrates into typical blood draw procedures utilizing venipuncture or newly placed peripheral intravenous lines and actively diverts and sequesters the initial aliquot of blood drawn (1.5 mL to 2.0 mL, recommended practice for diversion[31]) before opening an alternate sterile flow pathway to a blood culture bottle. Institutional Review Board approval was waived and participants were not required to provide informed consent in accordance with the minimal risk to participants throughout this quality improvement project.

The conventional method (CM) of sample acquisition for blood culture involved the alcohol pad-assisted disinfection of blood culture bottle (BacT/ALERT, bioMérieux, Marcy-l'Étoile, France) tops, preparation of the skin for venipuncture with a chlorhexidine gluconate solution, an avoidance of repalpation to minimize touch contamination and blood sample collection via venipuncture or newly placed peripheral intravenous line. ISDD utilization followed CM protocol but additionally integrated the ISDD into the vein-to-bottle pathway for blood sample acquisition. Emergency department staff, laboratory phlebotomists, and nursing staff on acute-critical care floors were trained in ISDD operating procedure and instructed to utilize the device for blood culture sample collection with adult (age 13 or

older) patients. ISDD training involved individual participatory demonstration followed by live draw observation, with a September rollout in the emergency department and an October rollout elsewhere. Staff were encouraged but not required to utilize the ISDD, and all sample acquisition without ISDD utilization (including that before intervention) occurred via the CM. ISDD utilization was tracked by laboratory personnel as staff were instructed to submit the ISDD package label to the laboratory alongside blood culture bottles.

A BCC was defined in laboratory analysis (VITEK 2, bioMérieux, Marcy-l'Étoile, France) as the recovery of a low-virulence commensal organism from a single blood culture set (one or two bottles) when the same commensal organism was not recovered in another blood culture set drawn from the same patient within 24 hours. Low-virulence commensal organisms included any coagulase-negative staphylococci, *Bacillus* sp., *Corynebacterium* sp., *Cutibacterium* sp., *Micrococcus* sp., or viridans group streptococci.

The chi-squared test (with $P < 0.05$ significant) was employed to define significance, although comparing ISDD and CM-associated outcomes during the intervention period with one another and with the hospital-wide preintervention CM BCC rate (3.06%, n = 10923, July 2019 through June 2020). The ISDD-associated contamination rates and CM-associated contamination rates observed in the emergency department, phlebotomy lab, and acute-critical environments were applied to said environment's total blood culture sample size over the intervention period to project false-positive event observations in hypothetical "100% ISDD utilization" and "No Intervention" scenarios, respectively.

Results

Approximately 60% of blood culture sets were collected in the emergency department, whereas 24% were collected in the phlebotomy lab and the remaining 16% collected in the acute-critical care floors. The distribution of blood culture sets collected and contamination events observed throughout the intervention period is depicted in Table 1.

In the emergency department, the CM BCC rate of 3.94% differed from the ISDD BCC rate of 1.05% (chi-squared test $P < 0.00001$), with the ISDD BCC rate representing a 73% reduction in contamination events. In the phlebotomy lab, the CM BCC rate of 3.65% differed from the ISDD BCC rate of 0.09% (chi-squared test $P < 0.00001$), with the ISDD BCC rate representing a 98% reduction in contamination events. In the acute-critical care floors, the CM BCC rate of 4.63% differed from the ISDD BCC rate of 0.75% (chi-squared test $P = 0.000074$), with the ISDD BCC rate representing an 84% reduction in contamination events. Hospital-wide, the CM BCC rate of 4.06% differed from the ISDD BCC rate of 0.78% (chi-squared test $P < 0.00001$), with the ISDD BCC rate representing an 81% reduction in contamination events. Hospital-wide, the CM BCC rate of 4.06% did not differ from the preintervention CM BCC rate of 3.06% (chi-squared test $P = 0.082$). In all environments, the CM BCC rate was >3% threshold rate recommended by the Clinical and Laboratory Standards Institute. In all environments, the ISDD BCC rate was below this threshold. Figure 1 depicts the contamination rates observed in each environment alongside the hospital-wide rate, segregating CM, and ISDD groups.

ISDD utilization for sample acquisition varied month-to-month by environment. ISDD utilization ranged from 79% to 93% in the emergency department, 70% to 93% in the phlebotomy lab, and 57% to 96% in the acute-critical care floors. The consistency with which the ISDD was utilized for sample acquisition throughout the intervention period is depicted in Figure 2.

Throughout the 8-month intervention period, approximately 148 contamination events were prevented: 82 in the emergency department, 40 in the phlebotomy lab, and 26 in the acute-critical care floors. Projected contamination event counts at 0% and 100% ISDD utilization along with observed contamination event counts are depicted in Figure 3.

Discussion

The author observed that irrespective of environment and irrespective of staff skillset, a 73% to 98% reduced incidence of BCC, relative to CM outcomes,

Table 1. Distribution of Blood Culture Set Counts and Contamination Events by Environment and Sample Acquisition Method From September 2020 Through April 2021 at United Hospital Center (Bridgeport, West Virginia)

	Conventional method			Initial specimen diversion device		
Environment	**Sets (n)**	**False positives (n)**	**Contamination rate (%)**	**Sets (n)**	**False positives (n)**	**Contamination rate (%)**
Emergency department	533	21	3.94	2847	30	1.05
Phlebotomy lab	219	8	3.65	1114	1	0.09
Acute-critical floors	259	12	4.63	670	5	0.75
Hospital-wide	1011	41	4.06	4631	36	0.78

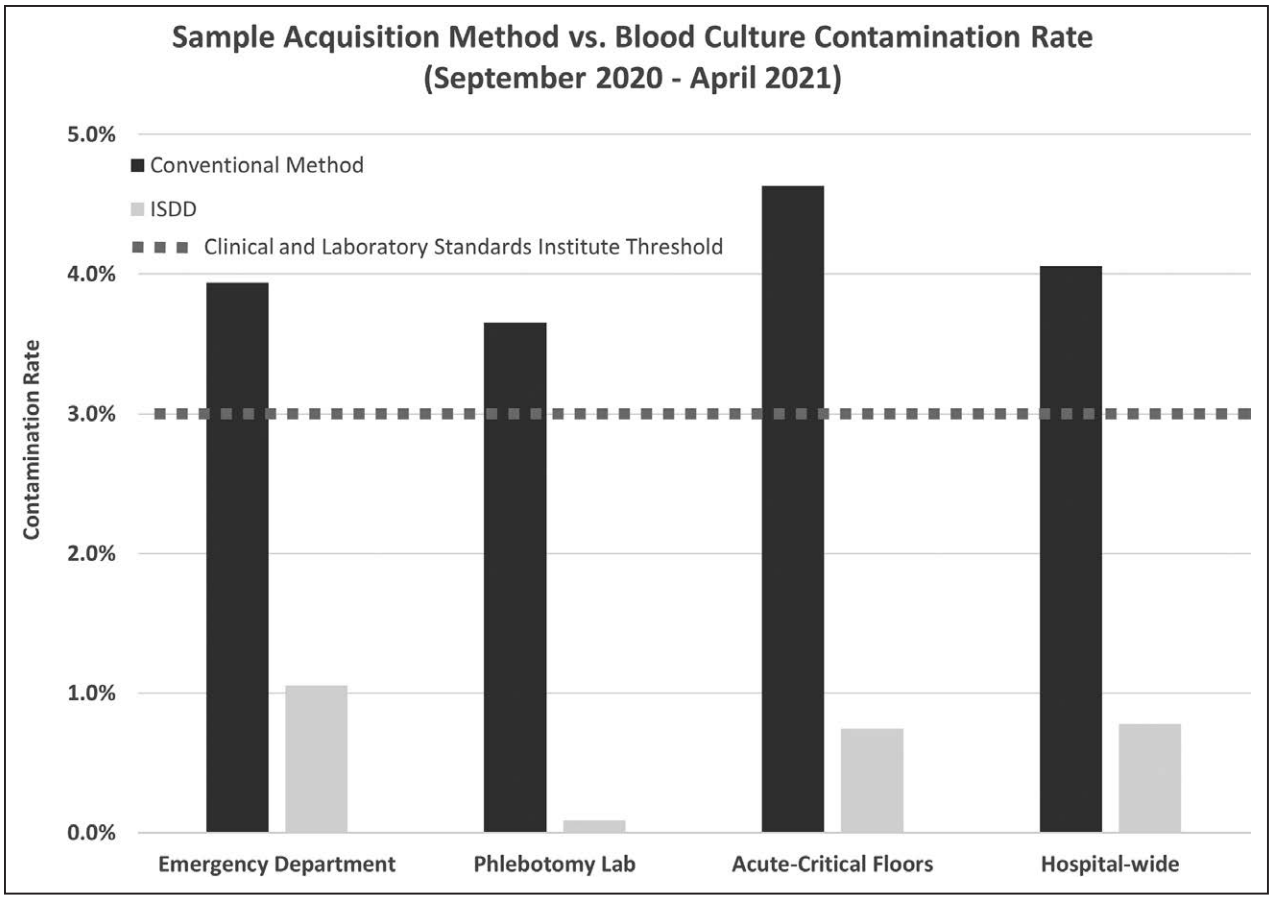

Figure 1. Observed blood culture contamination rates by environment and sample acquisition method set against the quality control benchmark recommended by the Clinical and Laboratory Standards Institute at United Hospital Center (Bridgeport, West Virginia).

was attributable to ISDD utilization. Throughout the intervention period, approximately 148 contamination events were prevented which, with sustained ISDD use, would amount to over 250 prevented contamination events annually at United Hospital Center and the preclusion of associated adverse events, assuming similar patient admittance postintervention.

False-positive blood cultures are immediately detrimental to patient quality of life and associated with length of stay increases commonly 2 to 5 days long.[3,32,33] Every single day of extension accompanies a 1.4% increase in the odds to acquire a health care associated infection, which typically extends length of stay by an additional week at minimum.[34] Antibiotic courses for patients impacted by contamination can last 1 to 2 weeks or more as diagnoses are resolved.[35] Patients placed on these unnecessary antibiotic regimens are at risk of having adverse events, with the incidence of acute kidney injury as high as 20% for the commonly administered combination of vancomycin and piperacillin-tazobactam.[36] *Clostridium difficile* infection is commonly associated with antibiotic administration (due to antibiotic alterations to gut flora) and can be fatal.[37] Exposure to unnecessary antibiotics is also associated with an increased risk of sepsis within 90 days of discharge.[38] The selective pressure of widespread antibiotic misuse is highly correlated with rises in antibiotic resistance,[39] and health care associated infections resulting from multidrug-resistant pathogens generate longer length of stay extensions and greater risks than antibiotic-susceptible pathogen infections.[40] Antibiotic misuse progresses an arms race that need not be happening, and this self-inflicted impetus to adopt policies and enforce protocols that embody antimicrobial stewardship principles threatens to outpace an ability to do so.

Proactive measures and innovative technology (such as the ISDD utilized herein) that systematically curtail antibiotic abuses should be celebrated. Financial incentives can reinforce an antimicrobial stewardship agenda, such as when payments are denied by the Centers for Medicare and Medicaid

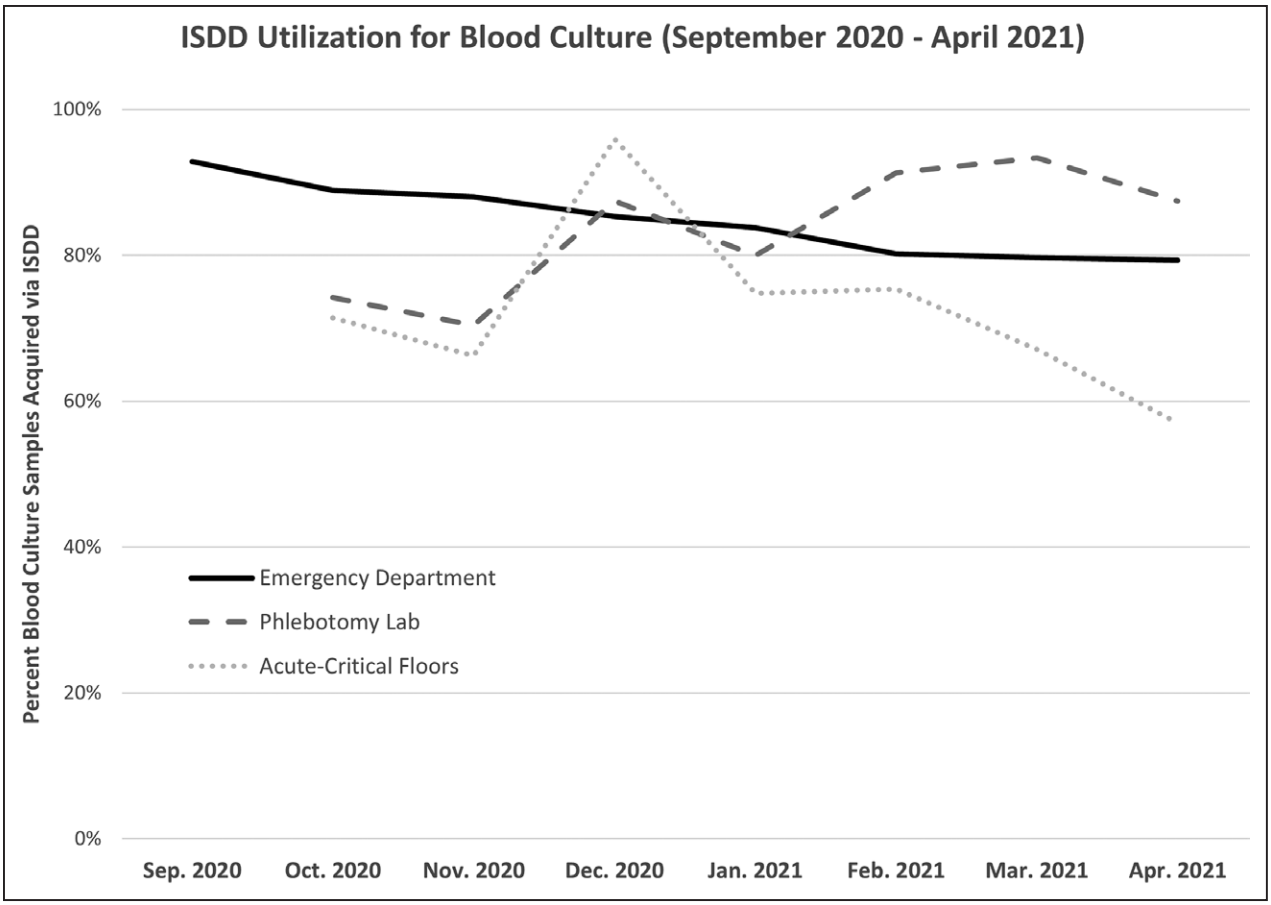

Figure 2. Percent of blood culture sets acquired with ISDD utilization for each environment throughout the intervention period at United Hospital Center (Bridgeport, West Virginia). ISDD indicates initial specimen diversion device.

Services (CMS) for health care associated infections or for testing deemed to have been unnecessary. False-positive central line-associated bloodstream infections must be reported to the National Healthcare Safety Network and CMS; fines and loss of CMS revenue may apply to facilities not operating within acceptable standards. The cost of a single BCC event to a health care system varies depending on the direct and indirect costs tallied, but the literature provides a range of $1400 to $8800.[3,14,15,32,33] As United Hospital Center assigns a $2100 figure to the cost of each BCC event the 148 false-positive blood cultures avoided throughout the intervention period represent over $310 000 in avoided expenses, not considering the cost of intervention. Although the West Virginia University Health System draws 90 000 blood cultures annually and stands to benefit substantially should the observed results translate to the entire system, a comprehensive assessment of intervention cost-effectiveness is best left to a future study.

A potential limitation of this study and these findings was the nonmandatory and nonrandomized utilization of the ISDD for blood culture. Although staff were strongly encouraged to use the device for all blood culture draws and ISDD utilization rates were high in all environments for the intervention period, it is conceivable that staff under higher stress loads or less assiduous staff opted out of ISDD adoption, and that ISDD and CM users and possibly their patients represented substantially different groups. As the BCC rate observed among the CM group during intervention was not significantly different from the preintervention BCC rate at United Hospital Center, the author does not believe this to be the case, but it must be noted as a limitation of the study that ISDD utilization rates of individual staff members and patient characteristics for ISDD and CM groups are not available to confirm this. A related potential limitation involved the method of reporting whether an ISDD was utilized or not for a given blood culture draw. A blood culture draw was only categorized into the ISDD group if a staff member kept and submitted the ISDD package label to the lab alongside the blood culture set as instructed.

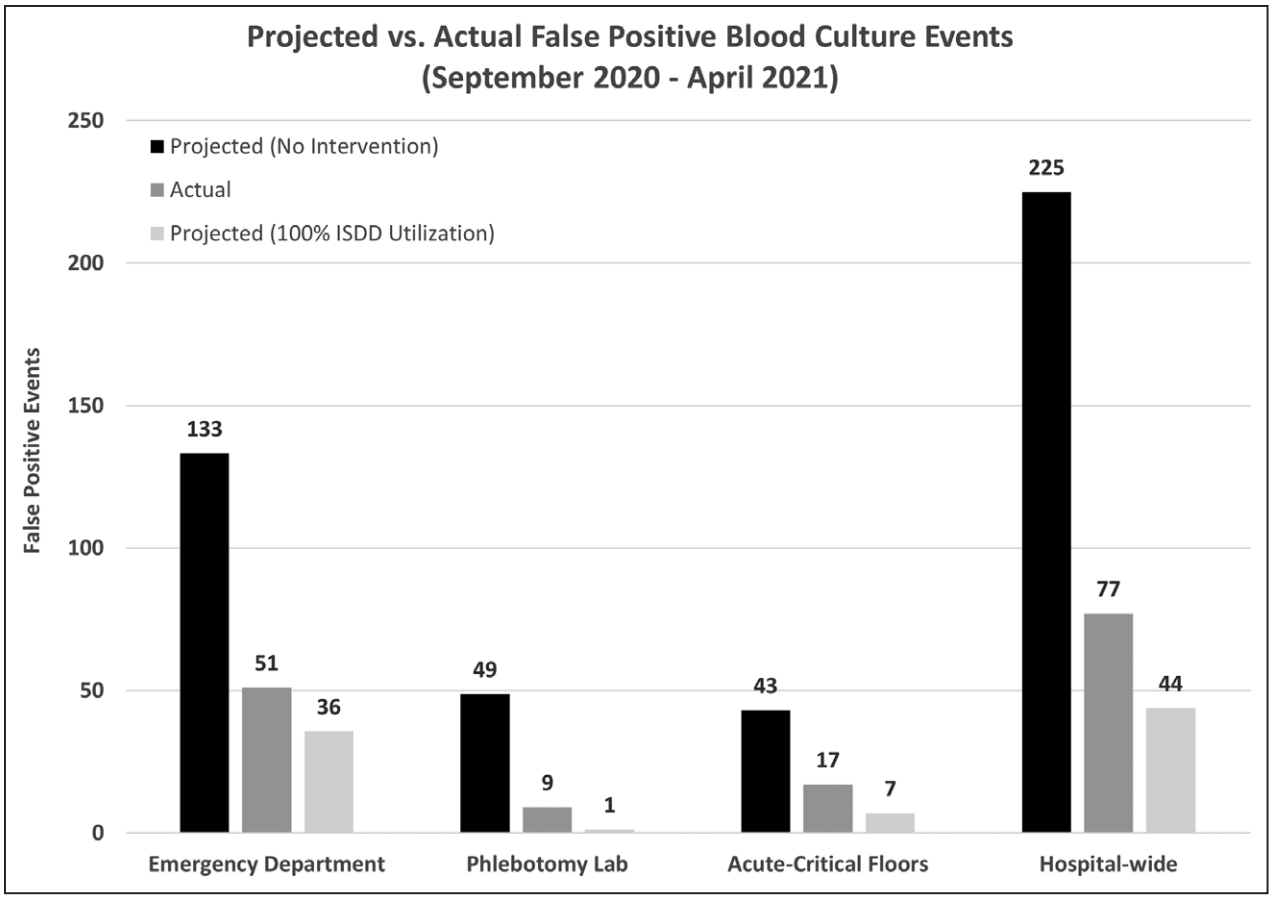

Figure 3. Projected vs actual false-positive blood culture events throughout the intervention period at United Hospital Center (Bridgeport, West Virginia), with projections assuming 0% and 100% ISDD utilization for the total set count. ISDD indicates initial specimen diversion device.

Staff could forget to submit the label, and so some ISDD sets could be counted as CM sets. The frequency at which this occurred, if at all, is unknown.

The nonideal conditions common to health care environments (particularly throughout the COVID-19 pandemic) compromise quality care and antimicrobial stewardship efforts when strict protocol yields to urgency and emergency. The author is pleased to find with ISDD utilization an innovative solution to a longstanding diagnostic shortcoming of blood culture resistant to human error. United Hospital Center now considers ISDD utilization standard practice hospital-wide for blood culture sample acquisition, and the results herein have empowered system value analyses for collaborators throughout the West Virginia University Health System.

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Conflicts of Interest

The author has no conflicts of interest to disclose.

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