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Continuous Quality Improvement for Introduction of Automated Blood Culture Instrument

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Despite the critical nature and high cost of blood cultures, hospitals rely on manufacturers' test site data. As a result, in-hospital testing and compliance evaluation of newly acquired instruments are seldom done. The goal of this study was to apply a continuous quality improvement approach and to develop assessment criteria for all stages from the purchase order, through the on-site instrument evaluation, to the compliance evaluation. Despite the introduction of an automated high-blood-volume instrument (BacT/Alert) in our hospital, 56% of adult patients had only one venipuncture and 89.5% had ≤20 ml of total blood volume sampled. False positives were associated with overfilling of bottles. These problems occurred because the phlebotomists did not like to perform multiple venipunctures on ill patients; therefore, they were drawing 20 ml of blood from one venipuncture and splitting it between two bottles. Unknown to the staff, the vacuum in the bottles draws significantly more than 10 ml of blood; therefore, the first bottle in the set was frequently overfilled and the second bottle was frequently underfilled. A diagrammatic guideline for a new blood culture protocol based on two venipunctures, taken one immediately after the other, to inoculate three bottles was developed. Compliance evaluation demonstrated that within 1 month of starting the new protocol, 74% of patients had at least two or more venipunctures and 60% had ≥30 ml of blood drawn per patient episode. This study demonstrates the need for continuous quality improvement, including compliance evaluation, to ensure that the potential benefits of newer blood culture technology are actually realized.

Blood cultures are one of the most significant single tests performed in the microbiology laboratory (2, 21) and can account for up to 10% of the total microbiology supplies budget. Recently, many "new-technology" automated blood culture systems have been introduced (14, 17, 19, 24, 26). Despite the critical nature of this test, there is generally heavy reliance on the manufacturer's test site evaluation and little reliance on local in-hospital assessment. Indeed, in some centers, blood culture instruments are brought on-line and used immediately for patient samples throughout the entire hospital with little or no evaluation of effectiveness or compliance with the new system. The need to more closely evaluate blood culture instruments is reflected by the tighter Food and Drug Administration criteria now being applied to new blood culture systems (6) and the pressure that tighter budgets have had on justifying instrument purchases and procedure changes. Similarly, many laboratories are recognizing the importance of evaluating compliance (8) with volume (9, 10, 15) and skin disinfection (20) guidelines. Robinson (16) has recently reviewed the impact of new technology on overutilization in diagnostic laboratories and has identified the need to critically assess whether such changes actually benefit patient care. Similarly, Bartlett et al. (1) have identified the need for better management of quality in microbiology laboratories. They identified blood volume and number of venipunctures as important issues to assess. However, little information is available to help guide laboratories in their quest for continuous quality improvement (CQI) of blood culture systems.

The aim of this study was to develop a standardized CQI approach to ensure that the new-technology blood culture instrument that we had purchased met our expectations. Through compliance evaluation as part of CQI, we identified inadequacies in the blood culture protocol that meant the advantages that the new automated system offered were not being realized.

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MATERIALS AND METHODS

Patient population. Our Microbiology Laboratory provides service to the St. Boniface General Hospital, which is a 600- to 650-bed tertiary care institution that is affiliated with the University of Manitoba. Blood cultures are received from patients for the following services: obstetrics and gynecology, general medicine, surgery and its subspecialties, critical care, family practice, geriatrics, psychiatry, dialysis, outpatient clinics, neonatology, and the emergency room.

Bacterial strains. The bacterial strains listed in Table 1 were tested. All aerobic and facultative bacteria were grown on blood agar consisting of tryptone soya agar base (Oxoid, Unipath Ltd., Basingstoke, Hampshire, England) supplemented with 5% sheep blood, except the fastidious species *Haemophilus influenzae*, *Haemophilus aphrophilus*, *Neisseria gonorrhoeae*, and *Neisseria meningitidis*, which were grown on chocolate agar consisting of GCII agar base (BBL, Becton Dickinson, Cockeysville, Md.) supplemented with 10 mg of hemoglobin per ml and XV supplement (PML Microbiologicals, Tualatin, Oreg.). All anaerobes were grown on blood agar with hemin and vitamin K_1, consisting of brucella agar base supplemented with 5% sheep blood and 10 μg of vitamin K_1 per ml and 5 μg of hemin per ml. Blood agar plates were incubated aerobically at 35°C, chocolate agar plates were incubated in CO_2 at 35°C, and anaerobic plates were incubated in an anaerobic chamber at 35°C. (Coy Laboratory Products, Inc., Ann Arbor, Mich.).

Quality control comparison of seeded organisms. In this study, sheep blood was seeded with bacteria to achieve a final concentration of 1 to 50 CFU/ml. Viable counts were performed with each inoculated blood sample to verify the actual number of CFU of bacteria per milliliter. The blood containing seeded bacteria was used to inoculate a BacT/Alert (Organon Teknika, Inc., Scarborough, Ontario, Canada) aerobic bottle and an anaerobic bottle (10 ml each), as well as a Bactec 660 (Becton Dickinson Canada, Inc., Mississauga, Ontario, Canada) aerobic bottle and an anaerobic bottle (5 ml each). Each bottle was placed into the appropriate instrument and monitored according to a 5-day protocol. All bottles were subcultured to chocolate agar (for *Haemophilus* spp.) or blood agar or blood agar with hemin and vitamin K_1 (for anaerobes) plates when they were identified as positive by the instrument or at the end of the 5-day protocol if they were not detected as positive (i.e., a terminal blind subculture was done with all bottles).

TABLE 1. Quality control test of the BacT/Alert instrument[a]

Organism	Source[b]	BacT/Alert			Bactec 660		
		Aerobic	Anaerobic	No. of h to positive result[c]	Aerobic	Anaerobic	No. of days to positive result
Fastidious							
Gardnerella vaginalis	Clinical isolate	+	+	67.2	−	−	
Haemophilus influenzae	Clinical isolate	+	+	13.3	+	+	1
Haemophilus aphrophilus	Clinical isolate	+	+	20.0	+	+	1
Neisseria gonorrhoeae	CDC 98	+	+	17.8	+	−	5
Neisseria meningitidis	Clinical isolate	+	+	14.8	+	−	1
Campylobacter jejuni	Clinical isolate	+	−	41.7	−	−	
				29.1 (avg)			
Gram positive							
Staphylococcus aureus	ATCC 25923	+	+	8.3	+	+	1
Staphylococcus epidermidis	ATCC 14990	+	+	9.7	+	+	1
Streptococcus pneumoniae	Clinical isolate	+	+	10.5	+	+	1
Viridans streptococci	Clinical isolate	+	+	13.0	+	+	1
Streptococcus pyogenes	Clinical isolate	+	+	9.2	+	+	1
Streptococcus agalactiae	Clinical isolate	+	+	7.8	+	+	3
				9.8 (avg)			
Gram negative							
Escherichia coli	ATCC 25922	+	+	7.3	+	+	1
Enterobacter cloacae	ATCC 13047	+	+	7.7	+	+	1
Klebsiella pneumoniae	ATCC 13883	+	+	8.0	+	+	1
Pseudomonas aeruginosa	ATCC 27853	+	+	10.8	+	+	1
Stenotrophomonas (*Xanthamonas*) *maltophilia*	Clinical isolate	+	+	15.5	+	−	3
Acinetobacter anitratus	Clinical isolate	+	+	11.8	+	−	3
				10.2 (avg)			
Anaerobes							
Bacteroides fragilis	ATCC 23748	−	+	72.0	−	+	NA[d]
Bacteroides uniformis	Clinical isolate	−	+	79.2	−	+	2
Clostridium perfringens	ATCC 13124	+	+	10.7	+	+	3
Fusobacterium sp.	College of American Pathologists Survey isolate	−	+	45.5	−	+	2
Peptostreptococcus sp.	ATCC 27337	−	+	57.6	−	−	
Propionibacterium sp.	ATCC 6919	+	+	69.6	−	+	4
				55.8 (avg)			
Yeasts							
Candida albicans	Microscan 66027	+	+	20.0	+	+	1
Torulopsis glabrata	Microscan 66032	+	+	22.8	+	+	1
Candida krusei	Clinical isolate	+	+	19.2	+	−	1
				20.7 (avg)			

[a] Sheep blood was seeded with test organisms to give a final concentration of ~50 CFU/ml (viable counts indicated that this ranged from 1 to 100 CFU/ml). Ten milliliters of the seeded blood was inoculated into each BacT/Alert bottle, and 5 ml was inoculated into each Bactec 660 bottle.
[b] All clinical isolates were from patients seen at our hospital.
[c] The shortest length of time either the aerobic bottle or anaerobic bottle was used.
[d] NA, not available.

Compliance evaluation. The flowchart depicted in Fig. 1 summarizes the many stages in the purchase, implementation, and evaluation process. The acceptance/rejection criteria set for the implementation stage were drawn from either in-house data (e.g., positivity rates), published data, or test site data. The criteria that we established for the purchase order included a positivity rate of ≥8%, a false-positivity rate of ≤2%, and a false-negativity rate of ≤0.5% (with no more than 25% of the false negatives being significant pathogens [e.g., members of the family *Enterobacteriacae*, *Staphylococcus aureus*, or *Streptococcus pneumoniae*]).

The three aspects of compliance for patient blood drawings with which we were concerned were (i) volume of blood sampled, (ii) number of venipunctures, and (iii) skin contamination rates (which reflect the degree of compliance with adequate skin disinfection guidelines). We adapted Mozes et al.'s (12) definition of a blood culture episode, and all of our data were evaluated on the basis of patient episodes, which were defined as blood specimens withdrawn for culture from one patient over a 24-h period.

Blood volume. Comparison of 100 aerobic and 100 anaerobic BacT/Alert bottles indicated that the average weights were 91.704 ± 0.511 and 89.150 ± 0.354 g, respectively. Comparison of weights for three different lot numbers indicated that, although there is some lot-to-lot variation, the intralot variation is not significant. In view of the low variability in the bottle weights within a given lot, we opted to weigh five bottles from each new lot and use this as the comparison standard. The weights of blood cultures from patients were measured upon receipt in the laboratory and compared with the expected weight for appropriately filled bottles from that lot. The limit of detection of deviation from the 10-ml filling protocol with this approach was calculated to be ±0.5 ml of blood because of the intralot variation among bottles. We accepted this limitation because variations in volume of blood drawn of <5% are unlikely to significantly impact positivity rates.

We also used the BacT/Alert computer database to establish how many bottles were drawn within the first 24 h and how frequently patients had blood cultures drawn on subsequent days.

Number of venipunctures. Data on the number of venipunctures had not been collected for the Bactec 660 instrument. The BacT/Alert computer allows the bottles to be entered as paired bottles or separate bottles. Aerobic and anaerobic

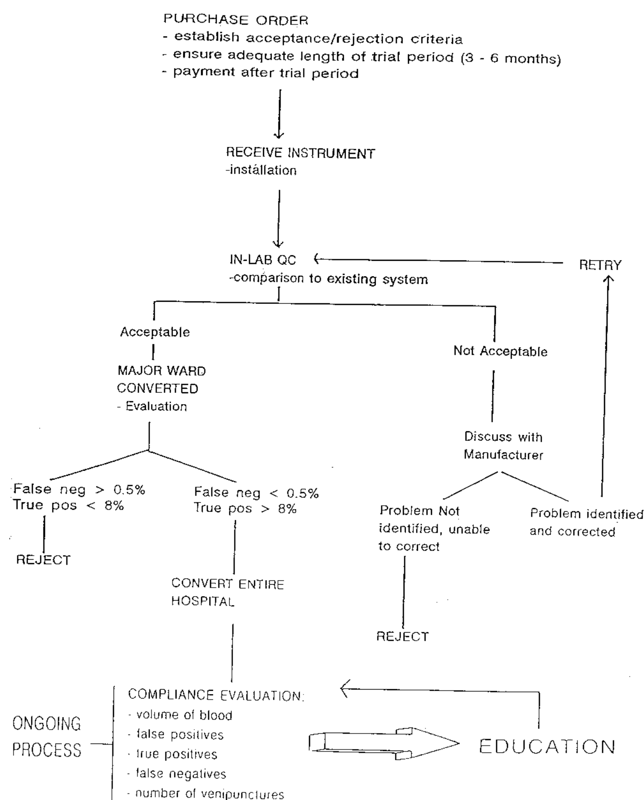

FIG. 1. Implementation and compliance evaluation of BacT/Alert blood culture system.

blood cultures drawn from the same venipuncture were entered as paired bottles under the same laboratory number. Bottles obtained from separate venipunctures were entered under unique laboratory numbers in the BacT/Alert database. This allowed us to easily determine for each patient the number of separate venipunctures, as well as the total number of bottles drawn each day. Analysis was based on the number of venipunctures per patient episode.

Contamination. Ideally, the establishment of an organism's clinical relevance or role as a skin contaminant requires complex assessments involving the individual patient's clinical status and chart review. We chose to make a generous assumption that 10% of all coagulase-negative staphylococci were significant isolates that would not be called skin contaminants. This takes into account the more significant role that coagulase-negative staphylococci play in neonatal septicemia and the increasing role that coagulase-negative staphylococci play as a nosocomial pathogen in bacteremic adults. In addition, *Bacillus* sp., *Propionibacterium* sp., and diphtheroids were included as potential skin contaminants unless they were detected in blood from ≥2 separate venipunctures. This assumption then allowed us to easily compare the skin contamination rates (i.e., false positives in which an isolate of no clinical relevance is grown because of skin contamination of the venipuncture sample) of the Emergency Department with those of the rest of the hospital. These searches were all done with the BacT/Alert software capabilities.

RESULTS

The overall algorithm for implementation is given in Fig. 1. Although the various aspects of the purchase order are normally handled by the purchasing department, it is crucial that the microbiology laboratory establish what the acceptance and rejection criteria should be and that these criteria be incorporated as part of the purchase order. Another crucial aspect that will ensure that your laboratory is not left "holding a lemon" is to ensure an adequate trial period (usually 3 to 6 months) for evaluation of the instrument prior to actual payment. Alternatively, sufficient guarantees must be documented to ensure that a full price refund will be given if the instrument does not meet specifications.

Once the instrument has been installed, stage 1 in the evaluation process is the in-laboratory quality control evaluation. The manufacturers of the BacT/Alert blood culture system do provide a list of organisms tested in this automated system. Because each hospital has its own unique patient population, it is important to ensure that the organisms that are most commonly isolated or that are of particular importance in the individual hospital are tested to ensure that they will be detected at least as well as they are in the system that is being replaced. The average number of CFU of bacteria per milliliter of blood in adults is generally low, with approximately 59% of adults having ≤10 CFU/ml (3, 7, 23, 25). In children, the bacterial load is heavier, because approximately 73% will have >10 CFU/ml (3, 21). Quality control testing should be performed in the lower range (target of 1 to 50 CFU/ml), because low bacterial loads are normally the most difficult to detect. The BacT/Alert system is based on detection of CO_2 generation; therefore, testing excessively high bacterial loads (e.g., 10^6 CFU/ml) is not only inappropriate, because humans do not attain these concentrations, but may even be misleading, because the culture may be in stationary phase and may not generate sufficient CO_2 to be detected by the instrument.

Table 1 lists the organisms that were tested in our laboratory. In our center, we see a wide mix of patients that includes adults and neonates. This list could be adapted for a specific patient population (e.g., laboratories with a large AIDS population may want to expand the list of the fungi tested).

Comparison of the BacT/Alert with the Bactec 660 identified only two major discrepancies (i.e., growth in at least one of the BacT/Alert bottles and no growth in any of the Bactec 660 bottles), involving *Gardnerella vaginalis* and *Peptostreptococcus* sp. (Table 1). Comparison of the inoculum for the BacT/Alert bottle (10 ml of seeded blood) with that for the Bactec 660 bottle (5 ml of seeded blood) indicated that there was between 5 and 250 CFU inoculated into each Bactec bottle (compared with between 10 and 500 CFU inoculated into each BacT/Alert bottle). The blind subcultures were negative for both Bactec 660 bottles, indicating that, despite the inoculation of these organisms into the bottle, no growth had occurred. Previous studies have indicated that *G. vaginalis* does not grow in the Bactec 660 bottle. Not only did the BacT/Alert system support a wider range of organisms, but the time to detection was significantly shorter (Table 1). This was particularly evident for the nonfermenters. These data indicated that the large-volume BacT/Alert system was superior to our existing Bactec 660 system.

The second stage in the evaluation was to convert a major ward in the hospital (Fig. 1). This phasing in was felt to be optimal to ensure that if a problem was identified, the new blood culture system could be rapidly removed and the old system reinstated. This would be extremely difficult if the whole hospital were converted at one time. We chose to convert our Emergency Department because it generates about 37% of all our blood cultures. Again, it is important to establish a set of parameters to be evaluated at this stage. Table 2 outlines the parameters that we compared. Because the Bactec 660 was instituted many years ago with no in-hospital evaluation and because we did not perform routine blind terminal subcultures, the false-negativity rate for the instrument was not known. In this part of the evaluation, "growth positive" simply refers to growth of microorganisms and does not consider the clinical significance of the organism. "False growth positive" refers to bottles that the instrument calls positive but that showed no organisms on Gram staining and from which no bacteria grew on subculture. "Growth negative" indicates that the instrument did not detect growth and that the terminal

TABLE 2. Comparison of blood culture-positive and -negative rates for the Bactec 660 and BacT/Alert systems

Parameter	No. (%) of bottles	
	BacT/Alert (n = 1,834)[a]	Bactec 660 (n = 1,026)[b]
Growth positive	226 (12.3)	91 (8.9)
False growth positive	22 (1.2)	205 (20)
Growth negative	1,579 (86.1)	730 (71.1)
False growth negative	7 (0.4)	Not done

[a] Data obtained 1 September 1993 through 28 February 1994 (6 months).
[b] Data obtained 1 January 1992 through 30 June 1992 (6 months).

blind subculture showed no growth. "False growth negative" indicates that the instrument did not detect growth but that organisms did grow when a blind subculture was performed. This was not a concurrent comparison; therefore, statistical comparisons may not be totally appropriate. However, it appears from this small comparison that the BacT/Alert met and exceeded the parameters evaluated for the existing Bactec 660 system with respect to detecting growth of organisms and not incorrectly calling samples positive (Table 2). The five organisms detected with the terminal blind subculture (false growth negative) for the BacT/Alert were all coagulase-negative staphylococci or *Propionibacterium* sp. that grew in the last 2 days of the 5-day protocol. In all cases, these were deemed to be skin contaminants by the attending physician in the Emergency Department.

The new instrument had met all of the evaluation criteria that we had established, and therefore the entire hospital was converted to the new system. Appropriate notification of the new system and information about the changes in procedure required were circulated to all staff and all wards via a newsletter and teaching sessions.

The final stage in the CQI approach was to analyze the compliance with the new system. Again, appropriate criteria were first established for compliance evaluation. We chose to investigate three aspects. (i) Was 10 ml of blood actually being injected into the bottles? (ii) Was skin contamination a problem? (iii) Were separate venipunctures being performed? To assess the first aspect, we opted to weigh all blood culture bottles upon receipt in the microbiology laboratory. Using the approach outlined in Materials and Methods, we wanted to determine if the bottles that we were receiving were within 2 ml of the ideal 10-ml target. Figure 2 indicates the compliance of various wards within our hospital. In every ward indicated, there was overfilling of the anaerobic bottles and underfilling of the aerobic bottles. Discussion with the members of the staff performing the blood culture drawings provided an explanation for this unusual trend. The members of the staff were very hesitant about "poking" ill patients any more frequently than they absolutely had to, and as a consequence, they were opting to do a single venipuncture and drawing 20 ml of blood, which was then split between the aerobic and anaerobic BacT/Alert bottles. Furthermore, they were unaware that the BacT/Alert bottles would draw in up to 18 ml before the vacuum was depleted. Our old procedure directed them to always inoculate the anaerobic bottle first. This was done to ensure that if only one venipuncture was achieved (i.e., they were unable to get the second venipuncture), then the sample would be in the anaerobic bottle, which was felt previously to be the best bottle because it would support the growth of anaerobes, facultative anaerobes, and, to some extent, strict aerobes. This set the scene for habitual overfilling of the anaerobic bottles, because

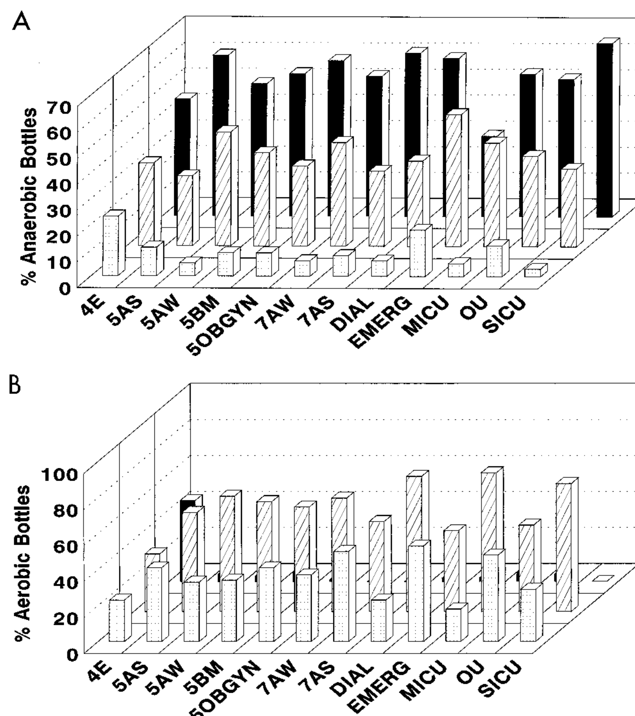

FIG. 2. Volume compliance for BacT/Alert anaerobic (A) and aerobic (B) blood culture bottles. Stippled bars, underfilled; hatched bars, correctly filled; solid bars, overfilled. Abbreviations represent specific wards or units as follows: 4E, Geriatric Ward; 5AS and 5AW, 5A South and 5A West, respectively (General Medicine); 5BM, 5B Medicine (General Medicine); 50BGYN, Obstetrics and Gynecology; 7AW and 7AS, 7A West and 7A South, respectively (Surgery); DIAL, Dialysis; EMERG, Emergency Department; MICU, Medical Intensive Care Unit; OU, Observation Unit; and SICU, Surgical Intensive Care Unit.

the staff would withdraw 20 ml with a syringe and inject into the anaerobic bottle first and allow it to draw in blood until the vacuum was depleted before filling the aerobic bottle with the remaining sample. The average volume of blood in the overfilled anaerobic bottles was 16 ± 3.9 ml (range, 12.2 to 26.1 ml).

When we assessed our data for false-positive bottles on the BacT/Alert instrument, we found that the false-positive rate was appreciably lower for the BacT/Alert system than for the existing Bactec 660 system (Table 2). However, we found that 16 of 17 (95%) of the BacT/Alert false positives were in overfilled anaerobic bottles. This suggests that the large blood volume probably has sufficient CO_2 generation from leukocyte respiration to be detected by the instrument. It is apparent from these data that, despite notification and instructions regarding the new system, we were getting poor compliance with the guidelines for the appropriate volume of blood to be injected into the BacT/Alert bottles.

The second criterion evaluated was compliance with separate venipunctures. Ideally, at least two separate venipunctures should be taken to ensure that, if a positive blood culture is detected, the issue of skin contamination can be assessed by checking whether more than one venipuncture grew the same organism. The likelihood that two separate venipunctures will grow the same organism as a result of skin contamination is exceedingly low. If only one bottle from two separate venipunctures grows coagulase-negative staphylococci, it is generally considered less significant than if two bottles from two separate venipunctures grew the organism. The clinical picture of the

TABLE 3. Data for old blood culture protocol[a]

Parameter	No. (%) with given characteristic for:	
	Bactec 660 (5 ml/bottle)	BacT/Alert (10 ml/bottle)
Patient episodes	2,638	1,682
Amt of blood collected/ patient episode		
1 bottle	235 (8.9)	114 (6.8)
2 bottles	1,943 (73.7)	1,391 (82.7)
3 bottles	52 (2.0)	18 (1.0)
4 bottles	344 (13.0)	144 (8.6)
≥5 bottles	64 (2.4)	15 (0.9)
No. of venipunctures/ patient episode		
1 only	NA[b]	933 (55.5)
2 or more	NA	749 (44.5)
Total vol of blood/ patient episode		
≤20 ml	2,574 (97.6)	1,505 (89.5)
≥25 ml	64 (2.4)	177 (10.5)

[a] Comparison of number of venipunctures and volume of blood submitted for the Bactec 660 and BacT/Alert systems under the old blood collection protocol. The old blood culture collection protocol consisted of six venipunctures and the drawing of three sets of blood. (A set is one aerobic bottle and one anaerobic bottle, each from a separate venipuncture.) There was to be a 30- to 60-min interval between collection of separate sets.

[b] NA, not available. Note that 23% of the venipunctures were documented from separate sites; the others had no documentation, and therefore complete data were not available.

patient must always be taken into consideration when these decisions are made. We analyzed our existing Bactec 660 data and 3,842 bottles from the BacT/Alert system (Table 3). Again, the underlying hesitancy of the staff to perform multiple venipunctures on ill patients is apparent, because 82.6% of adult patients who had blood cultures drawn for the Bactec 660 system had two or fewer bottles drawn (i.e., ≤10 ml of total blood tested). Of these, only 23% were documented to be from separate sites. Analysis of 1,682 bottles collected from adults for the BacT/Alert system indicated that 89.5% had two or fewer bottles drawn (i.e., ≤20 ml of total blood tested); of these, only 44.5% were documented from separate sites. The number of samples that were from either a single venipuncture site or an unspecified number of sites that were submitted as the only blood culture workup for the BacT/Alert system (55.5%) was unacceptably high (Table 3).

The third compliance criterion evaluated was the amount of skin contamination. Comparison by ward indicated that the Emergency Department had the greatest contamination rates. Table 4 summarizes the comparison of the Emergency Department with the rest of the wards in the hospital. In this table, the false positives were broken down to indicate the following: (i) no growth, the number of bottles that the machine detected as positive but that showed no organisms on Gram staining and did not grow any bacteria; and (ii) skin contaminant, those bottles that grew what were considered to be skin contaminants. It is apparent that the Emergency Department has double the rate of skin contamination compared with the rest of the hospital. The primary reason for high skin contamination rates in the Emergency Department appears to be related to staff members not allowing the povidone-iodine solution to remain in contact with the skin long enough prior to drawing the blood sample. Despite repeated attempts to emphasize the

TABLE 4. Comparison of blood culture contamination in the Emergency Department with that in the rest of the hospital

Parameter	No. (%) of cases of contamination in[a]:	
	Emergency department (n = 1,422)	Hospital excluding Emergency department (n = 2,420)
True positive[b]	134 (9.4)	179 (7.4)
False positive		
No growth	17 (1.2)	29 (0.9)
Skin contaminant	112 (7.9)	80 (3.6)
Total	129 (9.1)	109 (4.5)
True negative	1,157 (81.3)	2,132 (88.1)

[a] Rates are based on data collected between 1 December 1992 and 31 August 1993. Data represent 3,842 bottles (1,422 from the Emergency Department and 2,420 from the rest of the hospital.

[b] We made the assumption that all coagulase-negative staphylococci from the Neonatal Intensive Care Unit were significant and that 10% of all other coagulase-negative staphylococci were significant.

need to allow the povidone-iodine to dry on the skin (about 3 to 5 min), contamination rates remained at approximately 8%. Discussion with nursing staff indicated that the high-pressure environment of the Emergency Department precluded consistent compliance with this step.

As part of our CQI approach, there was a great deal of discussion with the staff members drawing the blood samples. It was apparent that a major problem with blood culture sampling is that no one likes to perform a venipuncture on an ill patient more than once, so despite clear instructions requiring separate venipunctures and collection of six bottles for the Bactec 660 system, most staff did not follow these guidelines. This is an understandable human response to what is an unpleasant procedure. Additionally, evaluation of why we had low levels of compliance with two separate venipunctures indicated that a compounding factor was that the staff members drawing blood had no way of knowing if other samples had been drawn and there was no communication that additional venipunctures were needed to complete the required number of sets, and, therefore, the additional venipunctures were not performed.

On the basis of the inadequacies identified, we developed an alternative approach to drawing blood culture samples that we felt would help improve the compliance rates. Figure 3 represents a visual guide we developed that was posted in all wards and that was included in the nursing procedure manual of our hospital. For a septic event, we are recommending that two venipunctures be done. The first draw consists of 20 ml, which is split between an aerobic bottle and an anaerobic bottle; the second draw consists of 10 ml, which is injected into an aerobic bottle. We have included a table that indicates what blood cultures should be drawn, dependent upon the type of suspected underlying infection (Fig. 3). The critical points regarding skin preparation, the need for two venipunctures, and the volume of blood have been emphasized. In addition to providing this graphic instruction sheet, we have also conducted continuing education sessions to help staff understand that they were providing suboptimal patient care if only one venipuncture was performed. We evaluated our compliance in the first 23 days after the protocol change and again in the second month (Table 5). Within the first 23 days, we documented a shift from 44.5% of patients having two or more venipunctures (Table 3) to 57.9% (Table 5). This improved even further to 73.6% (Table 5) by the second month.

BLOOD CULTURE INDICATIONS:

	Bacteremia Septicemia	Endocarditis	Fungal or Mycobacterial
1st Draw	Aerobic & Anaerobic Bottle	Aerobic & Anaerobic Bottle	Aerobic & Anaerobic Bottle
2nd Draw	Aerobic Bottle only	Aerobic Bottle only	Lysis Centrifugation tube
3rd Draw	Not necessary	Aerobic Bottle only	Lysis Centrifugation tube

BLOOD DRAW METHOD:

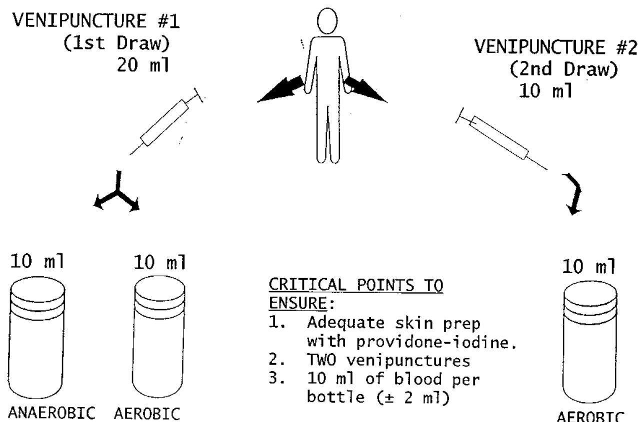

FIG. 3. Blood culture procedure for adults. Note that both venipunctures were done one immediately after the other.

TABLE 5. Data for new blood culture protocol[a]

Parameter	No. (%) with given characteristic with BacT/Alert during:	
	1–23 March	23 March–14 April
Patient episodes	145	204
Amt of blood collected/patient episode		
1 bottle	6 (4.1)	9 (4.4)
2 bottles		
Same venipuncture	55 (37.9)	45 (22.1)
Separate venipunctures	23 (15.9)	28 (13.7)
3 bottles (new protocol [2 venipunctures])	40 (27.6)	92 (45.1)
3 bottles (3 separate venipunctures)		14 (6.9)
≥4 bottles (≥2 venipunctures)	21 (14.5)	16 (7.8)
No. of venipunctures/patient episode		
1 only	61 (42.1)	54 (26.4)
2 or more	84 (57.9)	150 (73.6)
Total vol/patient episode		
≤20 ml	84 (57.9)	82 (40.2)
≥30 ml	61 (42.1)	122 (59.8)

[a] Comparison of number of venipunctures and volume of blood submitted for the BacT/Alert system under the new blood collection protocol. The new blood culture collection protocol consisted of two venipunctures. The first venipuncture consisted of 20 ml, which was split between an aerobic bottle and an anaerobic bottle, and the second venipuncture consisted of 10 ml, which was inoculated into an aerobic bottle. The venipunctures were performed one immediately after the other, and there was no defined interval between the collections.

DISCUSSION

Our experience has confirmed the need to employ a CQI approach for blood culture instrument introduction, integration, and compliance evaluation. Not only did this approach ensure smooth integration, but it also allowed us to identify compliance problems unique to the new system (overfilling of anaerobic bottles) and ones that had existed prior to the new system (lack of compliance with the number of separate venipunctures and problems with skin contamination). The need for continuing education cannot be overemphasized. The increasing sophistication of the semi- and fully automated blood culture systems requires ongoing compliance monitoring to ensure that the benefits that these instruments and culture methodologies offer are truly realized. The need for such a critical implementation approach has been reviewed by Robinson (16) and Bartlett et al. (1). New technology presents a unique cost containment dilemma. Uncritical application of new technology is unacceptable, particularly if compliance with the new technology protocols is poor and results in the expected benefits not being realized.

Because one of the major advantages of the BacT/Alert system is the improved positivity rate due to the larger volume of blood sampled, it is critical to evaluate whether members of the staff are actually injecting the correct volume. Simply by making a new large-volume-draw bottle available to the ward does not ensure that the correct volume of blood will be injected. Previous reports have indicated that suboptimal blood volumes are often submitted (5, 10, 15, 22). Porter et al. (15) reported that effecting changes in the blood culture volumes obtained is difficult to achieve. Indeed, Mermel et al. (10) recommend that all laboratories should, on an ongoing basis, monitor the weight of blood culture bottles as a means of monitoring the volume of blood received. Although preweighing of bottles as performed by Porter et al. (15) is the ideal approach, we feel that, provided the intralot variability in bottle weight is low, weighing the bottles once filled and received in the laboratory and comparing this with the expected weight derived by averaging the weight of a sample from the same lot is a reasonable and cost-effective approach to monitoring compliance with guidelines for the volume of blood taken. This latter approach cannot be used to assess small differences in blood volume, but it is a very practical means of assessing if major problems with overfilling or underfilling are occurring. Indeed, in these days of economic restraint when staff time is tightly monitored, it may be the only feasible way to accumulate this type of data.

Performing venipunctures on ill patients is not a pleasant process; therefore, it is important to develop a protocol that is realistic yet still provides good diagnostic potential. There is little value in having a multivenipuncture protocol that is not followed. Similar lack of compliance with hospital blood culture protocols has been noted by others (1). Issues that need to be considered are whether a phlebotomy team is collecting these blood cultures or whether members of the ward staff perform these collections. Discussions with the appropriate group are critical to ensure they understand the logic of needing at least two venipunctures; otherwise, the "avoidance of performing multiple venipunctures on ill patients" attitude will detrimentally affect any written protocol. As discussed by Bartlett et al. (1), several approaches to the number of venipunctures and the timing of these collections have been advocated. Because every attempt should be made to draw a complete blood culture workup before initiation of therapy, it seems reasonable to take two venipunctures, one immediately after the other, and to inoculate these into three to four bottles. Indeed Li et al. (9) have shown that simultaneous collection of blood samples is as effective for detecting positive samples as using timed gaps ranging from 12 min to 2 h between collec-

tions. The choice of bottle type should be dictated by the in-hospital prevalence of anaerobes, because some groups have advocated stopping routine culture for anaerobes (11, 13). We chose to split the first venipuncture (20 ml) between an aerobic bottle and an anaerobic bottle and to inoculate the second venipuncture (10 ml) into an aerobic bottle. In centers that have chosen to discontinue routine anaerobic cultures, the anaerobic bottle could be replaced with an aerobic bottle. Again, the staff needs to be educated and needs to understand that the bottles are not designed for direct draw and as such will draw in much more than 10 ml before the vacuum is depleted. Attention to ensuring that the correct volume is injected is important. Although we were unsuccessful at decreasing the skin contamination rates in the Emergency Department, alternative skin preparation with tincture of iodine has been shown to reduce the skin contamination rates from Emergency Departments in other centers (20).

The ultimate CQI outcome measure would involve a measure of cost-effectiveness. In the case of a blood culture instrument, this could be done by comparing the total blood culture testing costs of new versus old technology with the total costs incurred by the hospital for bacteremic and/or fungimic episodes in patients. This type of analysis is very complex and was not done in this study; rather only laboratory-determined parameters were measured. This type of cost-effectiveness outcome measure is discussed in the College of American Pathologists *Q-Probes: Blood Culture Utilization Critique and Analysis* (18) and has been applied to microbiology by Doern et al. (4).

In summary, we have shown that a CQI approach will ensure smooth integration of new blood culture technology. Compliance evaluation and corrective action will ensure that the newly introduced instrument delivers the expected benefits. In addition, compliance evaluation is critical to identify and correct any inadequacies that have developed over the years. This needs to be ongoing to ensure that multiple venipunctures, adequate volume, and low rates of skin contamination are consistently achieved.

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