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Original Research Article

Implementation of diagnostic stewardship in blood culture laboratory: a large-scale interventional study in a tertiary care hospital, South India

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ABSTRACT

Background: Laboratories with well-established diagnostic stewardship program for culture and antimicrobial susceptibility test (C-AST) play a key role in guiding the clinicians to institute specific targeted therapy.
Methods: The study period was divided into three phases; pre-intervention phase, intervention phase and post-intervention phase. During the pre-intervention phase, the blood culture was performed by conventional methods. During the intervention phase, immense efforts were made for full-fledged implementation of all the components of intervention-educational intervention for microbiology and clinical team and automations for culture, workflow modifications for performing preliminary tests in parallel with reporting, enhanced reporting frequency and stage-wise communication of reports to the clinicians.
Results: There was a significant improvement in the isolation rate in the post-intervention phase (from 10.3% to 15.5%). There has been a steady decrease in mean turnaround time (TAT) of positive culture reports (from 85 to 45 h), which was in turn due to faster blood culture positivity, identification time and AST time. There was also significant improvement in clinical team performance on various parameters such as % of samples sent in pair, % of specimens with appropriate blood volume collected and % culture drawn before the antibiotic start.
Conclusions: Our observation shows significant improvement in the pathogen isolation rate as well as performance of both microbiology and the clinical team. Most patients with sepsis are critically ill, therefore, it is the responsibility of every clinical microbiologist to implement the highest standard of diagnostic stewardship in blood culture laboratory.

Keywords: Diagnostic stewardship, TAT, Automated ID and AST system, Sepsis, AST

INTRODUCTION

Antimicrobial stewardship program (AMSP) is a synchronized initiative that encourages the appropriate use of antimicrobials, improves patient outcomes, reduces antimicrobial resistance, and decreases the spread of infections caused by multidrug-resistant organisms.[1,2] According to integrated stewardship model, AMS comprises of 3 imperative arms: clinical stewardship, diagnostic stewardship and infection control stewardship.[1] While clinical and infection control stewardship arms aim at institution of appropriate antimicrobial therapy and specific infection control practices respectively, the diagnostic stewardship aims at optimizing the laboratory diagnostics to achieve better patient outcome.[1-3]

Diagnostic stewardship is defined as "coordinated interventions to improve use of micro-biological diagnostics in order to guide therapeutic decisions. It should promote appropriate and timely diagnostic testing including specimen collection, accurate pathogen identification and timely reporting of AST results to guide antimicrobial treatment".[1,4] Laboratories with well-established diagnostic stewardship program for C-AST play a key role in guiding clinicians to institute specific targeted therapy and infection control measures.

Blood culture is one of the most critical investigations performed at microbiology laboratory.[5] Most patients with sepsis and severe sepsis are likely to be extremely sick, infected with drug resistant bugs and expected to have a higher risk of in-hospital morbidity and mortality.[6] Therefore, it is particularly important to develop a robust diagnostic stewardship model for the blood culture laboratory division.

Diagnostic stewardship depends up on multiple factors-infrastructure support (e.g., automation in culture, identification and AST), provision of technician equipped 24x7 lab, improvement in workflow to generate early report (e.g., multistage reporting), enhanced reporting frequency, timely report delivery mechanisms and improved communication with clinicians through pathogen-directed anti-microbial stewardship (AMS) rounds. Unfortunately, majority of Indian microbiology laboratories lack many of these factors, which result into either poor-quality C-AST report and/ ineffective communication with clinicians, ultimately affecting therapeutic decisions. Therefore, this quality improvement study undertaken to evaluate impact of implementing diagnostic stewardship intervention in blood culture lab on performance of microbiology and clinical teams.

METHODS

Type of study

The type of study was interventional study.

Study place

Study conducted at diagnostic blood culture division, department of microbiology, Jawaharlal institute of postgraduate medical education and research (JIPMER).

Study period

Three years, August 2016 to July 2019 which was divided into three phases; pre-intervention phase (August 2016 to July 2017), intervention phase (August 2017 to July 2018) and post- intervention phase (August 2018 to July 2019).

Selection criteria

All blood culture bottles received in microbiology laboratory included in study. Blood culture bottles without appropriate labelling or mismatch between patient details on bottle as well as request form was excluded from the analysis.

This study was conducted as apart of routine investigation. No additional sample was collected as part of project. Ethical approval was not obtained as there were no active interventions which were done on a patient. It is purely a lab-based study and only samples received in laboratory were included for study analysis.

Procedure

Pre- intervention phase

During pre-intervention phase (August 2016 to July 2017), blood culture was performed using conventional blood culture bottles (biphasic brain heart infusion media), following which colony identification and AST were done by conventional biochemical test and disk diffusion test, respectively. Reporting was done once a day, on working days around 9-11 AM. Holiday reporting and evening reporting were not performed routinely. Reports were authorized in lab information system (LIS) by afternoon.

Intervention phase (Implementation of diagnostic stewardship)

During the intervention phase, immense efforts were made by the department of microbiology to implement diagnostic stewardship which involved cooperation of multiple stakeholders such as laboratory staff, clinical team and hospital administration. This phase took an extensive time of one year (August 2017 to July 2018) for full-fledged implementation of all the components of intervention which are discussed below such as educational intervention for microbiology and clinical team, automations for culture (BacT/ALERT), identification (MALDI-TOF) and AST(VITEK), direct-identification and direct-AST, workflow modifications for performing preliminary tests in parallel with reporting, enhanced reporting frequency and stage-wise communication of reports to the clinicians (Table 1).

Educational sessions were conducted for the resident doctors working in Microbiology laboratory about the importance of TAT, early reporting and authorization, improved communication with clinical team and bedside visits. The hospital administration had given tremendous support in providing technical manpower, funds for pan-automation in diagnostic blood culture such as BacT/ALERT® (for automated culture), matrix-assisted laser desorption/ionization-time of flight (MALDI-TOF) for automated identification and VITEK-2® for automated AST. Blood culture requisition form was revised with incorporation of steps of blood collection and having provision of filling the details of the paired samples collected in a single form. Blood culture register was changed from manual to electronic (excel based) register; which promotes faster and easier data analysis. Direct-identification and direct-AST one of notable interventions done to foster diagnostic stewardship. Direct-identification (ID) and direct susceptibility test by disk diffusion (direct-AST) were performed from positively flagged blood culture broth. To prevent delay in reporting, the preliminary tests were performed in parallel to reporting rather than after reporting. As result, interpretation of these tests was incorporated in report of same day. Blood volume of blood culture bottles was monitored and included as a part of C-AST report, so that clinicians would correlate between blood volume and culture result.

Table 1: Interventions implemented as a part of diagnostic stewardship.

Interventions	Pre-intervention phase	Intervention and post- intervention phases
Educational intervention for microbiology team	Not conducted	Conducted for the resident doctors about the concept of diagnostic stewardship, faster TAT, early reporting and effective communication
Automation		
Blood culture bottle	Conventional, biphasic media (BHI)	Automated blood culture bottle (BacT/ALERT®)
Bacterial Identification	Conventional biochemical reactions	MALDI-TOF
AST	Colony-AST (by disk-diffusion)	Direct-AST (by disk-diffusion) and colony AST (by VITEK®2)
Blood culture requisition form	Old requisition form, no steps of collection in the form, single sample per form	Revised requisition form which includes Steps of blood collection, emphasis on two samples with a single form
Blood culture register	Manual register	Excel based electronic register
Direct identification and direct-AST*	Not performed	Performed
Workflow modifications for performing preliminary tests: Culture Gram stain, LAT for *S. aureus*, 3% KOH test, catalase, oxidase	These tests were performed only after reporting is over. Therefore, interpretation of these tests incorporated in next day's report.	Preformed during the reporting time, in parallel. Therefore, interpretation of these tests incorporated in same day's report.
Blood volume monitoring	Not performed	Monitored and feedback given to the clinicians in daily culture report.
Reporting timing and frequency	Morning 9 AM-11 AM, no evening reporting, no holiday reporting	Morning 7.30 AM-9.30 AM, Evening reporting and holiday reporting
Stage-wise communication to clinicians	One stage communication only (final report): Colony identification and colony AST	Multistage communication, Preliminary report: Direct identification and direct-AST. Final report: Colony identification and colony AST
Report delivery	Laboratory information system (LIS), reports authorized at afternoon	LIS (reports authorized early, forenoon), additional mode of communications: Telephonic calls for critical reports, WhatsApp communication through release of the consolidated PDF immediately after reporting, personal bedside visits (Pathogen directed stewardship)
Educational sessions for clinical team	Not conducted	Educational sessions focusing on, steps of blood culture collection, appropriate blood volume, paired sample from different source, ** culture of cultures (i.e., sending culture before antibiotic start)

*Direct identification and AST performed from positively flagged blood culture broth; ** Paired blood sample from different source such as central line, and venepuncture. *Abbreviations:* AMSP, antimicrobial stewardship program; LAT, latex agglutination test; BHI, brain hearty infusion; MALDI-TOF, matrix-assisted laser desorption ionization time-of-flight mass spectrometry; direct-AST, direct susceptibility test by disk diffusion (direct-AST).

Reporting timing and frequency was one of the most important steps taken in the intervention phase. The morning reporting was conducted at an early time (7.30 AM-9.30 AM) so that the release of the report would synchronize with clinical team's round time. Evening reporting and holiday reporting were introduced so as to prevent the delay in reporting. Clinicians were communicated in multiple stages-first by preliminary report comprising of direct-identification and direct AST, followed by final report comprising of colony identification and colony-AST. In addition to reports being authorized and delivered to LIS (laboratory information system), further measures were taken for early communication to the clinicians through telephonic calls for critical reports, WhatsApp communication through release of the consolidated PDF immediately after reporting and personal bedside visits through pathogen-directed AMSP rounds. Several educational sessions were conducted for clinical team focusing on steps of blood culture collection, importance of collecting appropriate blood volume, drawing paired sample from different sources, and sending culture before antibiotic start.

Post-intervention phase

The elements of diagnostic stewardship implemented in intervention phase were continued to be maintained during the post-intervention phase (August 2018 to July 2019).

Statistical analysis

Data on various parameters in pre- and post-intervention phases were collected in Microsoft excel. Variables such as organism isolation rate, parameters monitored to assess microbiology and clinical team performances; for e.g., appropriateness of blood volume, contamination rate etc. were expressed in frequency and percentage. Data comparison between the pre- and post-intervention phases was carried out using the chi-square or Fisher exact test.

RESULTS

During the study period, about 18,754 and 31,099 blood cultures were received in pre- and post-intervention phase respectively. Impact of the intervention on isolation rate of microorganisms from blood culture has been depicted in Table 2. Total pathogen isolation rate was 10.3% and 15.5% in pre- and post-intervention phases respectively and there was a sustained increased in the isolation rate of all pathogen groups. Of note, fastidious organisms were isolated in higher frequency in post-intervention phase. Species level identification was improved to 96.7% in post-intervention phase, as compared to 68.4% in pre-intervention phase.

The impact of diagnostic stewardship intervention on the microbiology team performance has been depicted in Table 3. There has been a steady decrease in mean TAT of positive culture reports from 85 h in pre-intervention phase, to 45 h in post-intervention phase.

Agreement between direct Gram stain with culture was improved from 55% to 81%. There has been a significant reduction in the median time to positivity (TTP) of blood culture bottles (from 60 h to 17 h), median identification time (from 48 to 10 h) and median AST time (from 48 to 10 h preliminary and 28 h for final report) between pre- and post-intervention phases. About 76% of positively flagged blood cultures bottles had a TTP of <24 h in post-intervention phase, as compared to 5% in pre-intervention phase. The time period between reported manually and authorized in LIS (from 6.5 to 3.5 h) and reports authorized and action taken by clinicians (from 8 to 1 h) had also been noticed to be significantly declined between pre- and post-intervention phases. The effect of diagnostic stewardship intervention on clinical team performance has been depicted in Table 4.

Table 2: Impact on isolation rate of microorganisms from blood culture.

Organism distribution	Pre- intervention phase (2016-17) (%)	Post-intervention phase (2018-19) (%)	Difference (%)	P value
Total pathogen isolation rate	10.3 (1930/18754)	15.5 (4811/31099)	5.2	<0.001
Gram positive cocci (non-fastidious)	2.2 (420/18754)	3.02 (938/31099)	0.8	<0.001
Enterobacteriaceae	3.9 (724/18754)	5.5 (1711/31099)	1.6	<0.001
Non-fermenters	3.7 (686/18754)	5.51 (1714/31099)	1.8	<0.001
Fastidious, gram-positive*	0.2 (34/18754)	0.5 (144/31099)	0.3	<0.001
Fastidious, gram-negative**	0.005 (1/18754)	0.03 (10/31099)	0.03	0.04
Candida	0.4 (65/18754)	0.95 (294/31099)	0.6	<0.001
Species identification	68.4 (1321/1930)	96.8 (4656/4811)	28.3	<0.001

*Fastidious, gram-positive isolated includes beta hemolytic *Streptococcus*, *Pneumococcus*, nutritionally deficient *Streptococcus* and *Nocardia.* **Fastidious gram-negative isolated include *Haemophilus influenzae, Brucella, Cardiobacterium hominis.*

Table 3: Impact of diagnostic stewardship intervention on microbiology team performance for the positively flagged blood culture bottles.

Parameters monitored	Pre (hours)	Post (hours)	P value
Average TAT of positive culture report	85 (final)	27 (prelim),	<0.001
		45 (final)	<0.001
Median time to positivity TTP: Duration between blood culture bottle loaded in incubator and growth detected	60 (20-160)	17 (0.2-117)	<0.001
	<24-5%	<24-76%	<0.001
Median identification time: Duration between growth detected and final identification result made available	48	10	<0.001
Median AST time: Duration between growth detected and AST result is available	48	10 (direct-AST)	<0.001
		28 (colony-AST)	<0.001
Accuracy of direct gram stain finding	55%	81%	<0.001
Time between reports issued manually and authorized in the LIS	6.5	3.5	<0.001
Time between report authorized and action taken*	8 (4-22)	1 (0.2-3)	-

Table 4: Impact of diagnostic stewardship intervention on clinical team performance.

Parameters	Pre-intervention phase (%)	Post-intervention phase (%)	Difference (%)	P value
Appropriate blood volume sent[$]	Data not available	58.1 (14576/25075)	NA	-
Samples sent in pair	9.3 (1744/18754)	67.8 (21071/31099)	58.5	<0.001
Culture drawn before antibiotic start*	25	55	30	-
Source (central line or venepuncture) mentioned in the requisition form	5.2 (979/18754)	67.3 (20931/31099)	62.1	<0.001
Clinical diagnosis mentioned in the requisition form	58 (10871/18754)	71.8 (22341/31099)	13.8	<0.001
Attending clinician's detail mentioned in the requisition form	11.5 (2151/18754)	66.8 (20782/31099)	55.4	<0.001
Sample transport time <2 hr*	25	60	35	-
Hang over time <2 hr (culture decision to sample collection)*	20	75	55	-
Contaminant rate	10.7 (2011/18754)	14.4 (4463/31099)	3.7	<0.001

[$]In adult patients, *data is based on survey performed among the clinicians, NA Not applicable, therefore the p was not analysed.

DISCUSSION

Diagnostic stewardship is a state-of-the-art diagnostic which are performed timely, for right patients before initiating antimicrobial therapy.[1,2] Blood cultures being the most critically important and potentially life-saving culture and AST investigation, the implementation of diagnostic stewardship is a much-needed intervention in blood culture laboratories. Early delivery of quality culture and AST report will not only benefit the patient, but will also help to control the emergence of antimicrobial resistance by minimizing the use of broad-spectrum antibiotics and can also guide the nursing team to offer the suitable infection control measures. Keeping this in view, a multimodal intervention was designed to augment the diagnostic stewardship in blood culture division.

The 'pathogen isolation rate' was significantly improved in the post-intervention phase (from 10.3% to 15.5%, p<0.001), which may be attributed to several factors; of which the most important is use of automated blood culture system (BacT/ALERT® VIRTUO®). In concordance, several other studies have also documented a significant improvement in organism isolation rate when automated blood culture systems were used, as compared to conventional blood culture bottles; viz. Hasan et al (from 18.8% to 45.5%), Ahmad et al (from 24% to 36%), Chokephaibulkit et al (from 23% to 55%) and Abbas et al from 10.3% to 15.3%).[7-10] Continuous monitoring of blood culture systems offers several advantages over conventional blood culture media such as faster detection rate, higher isolation rate, and shorter incubation time of 5 days. All the three currently available automated blood culture systems such as BacT/ALERT® (bioMérieux), BACTEC® (BD) and BacT/ALERT® VIRTUO® (bioMérieux) have incubation chambers with automated agitation facility, achieved via rocking or vortexing.[7,9]

Upsurge in the isolation rate was observed in 'all three pathogen groups' gram-positive and gram-negative as well as yeast group. Of note, the isolation rate of fastidious organisms were significantly increased (p<0.001). The isolation of fastidious, gram-positive bacterial pathogens such as beta hemolytic *Streptococci*, *Pneumococcus*, nutritionally deficient *Streptococcus* and *Nocardia* improved from 0.2-0.5% (p <0.001); whereas the isolation of fastidious gram-negative isolates (e.g., *Haemophilus influenzae*) improved from 0.005% to 0.03% (p=0.04). Several fastidious pathogens such as *Nocardia, Brucella,* and *Cardiobacterium hominis* which were never reported in pre-intervention phase were isolated in post-intervention phase.

There was significant improvement in the 'species level identification' (from 68.4% to 96.7%) observed in post-intervention phase; which was definitely owing to the use of MALDI-TOF for identification of bacterial and yeast pathogens. The MALDI-TOF is revolutionary in clinical microbiology laboratories-the most essential equipment needed for implementing diagnostic stewardship. It not only detects faster (<1 min per isolate) but also with absolute precision.[11] Similar to our observation, several studies elsewhere in the literature have also reported a significant improvement in species level identification by the use of MALDI-TOF, when compared to conventional identification system; viz. Patel et al (from 75% to 93%) and Lau et al (reported 75% and 45% of the difficult-to-identify bacteria studied were correctly identified to the genus and species levels, respectively).[11,12] Accurate species identification is of immense value-first, it directs the laboratory about which antibiotics to be included in the AST panel and breakpoint to be used while interpreting the AST result (for e.g. Clinical and laboratory standards institute (CLSI) breakpoint used for pseudo-first, it *Monas aeruginosa* is different than that for other *Pseudomonas* species); secondly, it guides the clinicians to start appropriate antibiotics (for e.g. ceftriaxone for *Cardiobacterium*), and also gives information about intrinsic resistance (e.g. vancomycin for *Enterococcus gallinarum*) which otherwise would have been missed.[9,10] The 'total number of specimens received' during the study period itself was significantly increased from 18,754 to

31,099; which may largely be attributed to the several educational sessions conducted targeting the clinical team with special emphasis on collection of paired blood culture samples.

The impact of diagnostic stewardship intervention on microbiology team performance was evaluated. The 'average TAT' of the final report of positive culture was significantly reduced ($p<0.001$) from 85 h in pre-intervention phase to 45h in post-intervention phase. In addition, the TAT was further reduced to 27 h ($p<0.001$) by releasing a preliminary report, which comprised of direct Gram staining finding, identification and direct AST. Direct-AST from positively flagged blood culture broth is one of the prime components of diagnostic stewardship, especially in critically ill patients with sepsis, as it guides clinicians to modify empirical therapy, at least 18-24 h earlier compared to awaiting final report.[13,14] Both CLSI and European committee on antimicrobial susceptibility testing (EUCAST) strongly recommend the laboratories to report direct-AST for blood culture investigations.[12,13] A previous study from the same centre reported a categorical agreement of 96% between direct-AST and colony-AST, subsequent to which the preliminary reporting has been incorporated as a part of the routine processing in our blood culture laboratory.[15] There are numerous other studies in literature, which reported the immense value of direct-AST in guiding antibiotic management in critically ill patients.[13-18]

In our study, the substantial improvement in TAT can be attributed to all the three components of the laboratory workflow-culture, identification and AST. The 'median time-to-positivity (TTP)' was reduced from 60 h to 17 h in post-intervention phase (statistically significant, $p<0.001$). More so, 76% of the growth was observed within first 24 hours in post-intervention phase, compared to 5% in pre-intervention phase ($p<0.001$). The main reason could be because of continuous monitoring of bottles for growth (every 10 min) by automated culture system, as compared to manual inspection of visible growth in conventional bottles (performed once daily). In concordance, there were several studies which documented the role of automated blood cultures in faster detection of growth, measured in terms of median TTP of blood culture bottles. Lyngdoh et al.[19] reported that with use of automated blood culture system TTP drastically reduced from 66.9 h to 15.8 h. Several other studies also reported similar median TTP, example includes Kuzniewicz et al (17.1-25.3 h), Abdelhamid et al (21 h) and Guerti et al (21.3 h).[20-22] Similarly, the 'median identification time' was significantly reduced (from 48 h to 10 h, p value <0.001), attributed to the use of MALDI-TOF for identification in post-intervention phase. The 'median AST time' was also reduced substantially in post-intervention phase ($p<0.001$), which was because of performing direct-AST (by disk diffusion) and use of VITEK® 2, an automated AST system for performing colony AST. In concordance to our study, the role of MALDI-TOF for early detection and VITEK® 2 for faster release of AST report was applauded by several other studies.[1,2,10,23-27]

The 'accuracy of direct Gram stain finding' when compared with culture was significantly improved in post-intervention phase (55% vs 81%). Accurate Gram-stain finding is of immense help as it guides the laboratory in selecting the appropriate antimicrobial panel for performing direct-AST.[28] It was also noted that, there was a significant reduction in time (~ 3 h) between 'reports issued manually and authorized in HIS' in the post-intervention phase; which was mainly attributed to the efforts taken by the laboratory team to authorize early in LIS. The time between 'reports authorized on LIS and appropriate action taken' by the clinical team was also considerably reduced (~ 7 h). This was attributed to several factors-(1) reporting timing synchronized with the time of clinical rounds by doing early reporting in the morning before the clinical round commenced (2) early communication to the clinical team via telephonic calls for critical reports and through the release of the consolidated PDF immediately after reporting in the 'Micro-clinical WhatsApp group'; (3) conducting pathogen-directed AMS audit by personal bedside visits and communicating with the clinical team.

The implementation of diagnostic stewardship has also influenced the performance of the clinical team in our facility. Several educational sessions were conducted for clinical team which resulted in significant improvement in various parameters such as % of samples sent in pair, % of specimens with appropriate blood volume collected and % culture drawn before the antibiotic start. When samples are sent in pair (collected from two different sites) and in adequate volume (8-10 ml per adult and 1-3 ml per paediatric blood culture), it greatly increases the chance of isolation.[29] The concept of 'culture of culture' is critical for better yield of pathogens from the clinical specimens. It is recommended that the blood cultures should always be collected before the antimicrobial start. If patient is already on antimicrobial, then the specimen can be collected just before the next dose of antibiotic.

There was also a significant improvement in the 'filling of various parameters in the blood culture requisition form' such as source of the specimen, diagnosis and clinician's detail. Each of these components has a colossal role in clinical management of the patient

Survey taken among the clinicians revealed that there was a substantial improvement in the 'hang over time' (i.e., time between culture decision and sample collection) and 'sample transport time' (i.e., time between sample collection and sample receipt at the laboratory). Surprisingly, in our study, it is observed that the contamination rate was increased in post-intervention phase; which may be due to several factors, such as absence of dedicated phlebotomist for specimen collection, lack of standardised blood culture collection set, rotational posting of the junior doctors who are

primarily involved in specimen collection. Reducing the contamination rate is the target of improvement in our future research studies.

Limitations

This study has few limitations. Response to treatment post-release of blood culture report, could not be collected, which will be included as a component in future research. Impact of TAT on patient's prognosis, antibiotic usage was not done and will be included as a component of future research.

CONCLUSION

To the best of our knowledge, this is the first of its kind large scale study from India, where the impact of implementation of diagnostic stewardship was studied. We observed that there was a considerable improvement in the pathogen isolation rate and also in the performance of both microbiology and the clinical team. The authors urge that blood culture is the heart of diagnostic microbiology laboratory. Taking into consideration that, most patients with sepsis are critically ill and pose high morbidity and mortality, it is the responsibility of every clinical microbiologist to implement the highest standard of diagnostic stewardship.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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