



An initiative to improve effluent culture detection among pediatric patients undergoing peritoneal dialysis through process improvement

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Abstract

Background Peritonitis is a significant cause of morbidity and healthcare cost among pediatric patients undergoing peritoneal dialysis. Culture-negative peritonitis has been associated with an increased risk of technique failure. Known risk factors for culture-negative peritonitis are related to the process of collection and sample processing for culture, but additional studies are needed. A culture detection rate of 16.7% was identified among our patients undergoing peritoneal dialysis, which is below the national benchmark of $\geq 85\%$. Our primary objective of this quality improvement project was to improve culture detection rates.

Methods Interventions were developed aimed at standardizing the process of effluent collection and laboratory processing, timely collection and processing of samples, and addressing other modifying risk factors for lack of bacterial growth from culture. These interventions included direct inoculation of effluent into blood culture bottles at bedside and use of an automated blood culture system. Two Plan-Do-Study-Act cycles were completed prior to moving to the sustain phase.

Results The culture detection rate improved from 16.7% (pre-intervention) to 100% (post-intervention). A decrease in the median process time also occurred from 83 min (pre-intervention) to 53 min (post-intervention). An individual and moving range chart identified a decrease in both the centerline (mean) and upper control limit, indicating that the process became more reliable during the sustain phase.

Conclusions An improvement in process time and culture positivity rate occurred following standardization of our PD fluid culture process. Future studies should be aimed at the impact of the components of collection and processing methods on the effluent culture yield.

Keywords Quality improvement · Culture-negative peritonitis · Pediatric

Abbreviations

PD	Peritoneal dialysis
DIDTL	Diagnostic Infectious Diseases Testing Laboratory
SCOPE	Standardizing Care to Improve Outcomes in Pediatric End Stage Kidney Disease
CCHMC	Cincinnati Children's Hospital Medical Center

IQR	Interquartile range
X-MR chart	Individual and moving range chart

Introduction

Peritoneal dialysis (PD) is a life-saving intervention for children with stage 5 chronic kidney disease (CKD) and is the most common dialysis modality used in the pediatric population [1]. PD-associated peritonitis can be devastating for patients by increasing the risk of technique failure (i.e., permanent discontinuation of PD), additional healthcare costs, and unnecessary exposure to broad spectrum antibiotics [2, 3]. Dialysis centers therefore aim to maintain low rates of culture-negative peritonitis, and the International Society for Peritoneal Dialysis (ISPD) recommends that such events should represent $< 15\%$ of all peritonitis events within a center [4, 5].

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There is limited data regarding risk factors for culture-negative peritonitis, although those identified—such as culture methodology [6], dialysate culture volume [6], antibiotic use with 30 days, and collection by staff without dialysis specialty training [7]—are related to processes rather than intrinsic patient factors. The Standardizing Care to Improve Outcomes in Pediatric End Stage Kidney Disease (SCOPE) Collaborative, a collaborative of 51 North American institutions whose goal is to prevent dialysis-associated infections among pediatric chronic PD patients [8], reported an overall culture-negative peritonitis rate of 26.6%, with significant variability in culture-negative peritonitis rates and peritoneal effluent collection methods and processes among 32 surveyed centers, with our institution falling among the higher rates [9]. In order to reduce culture-negative peritonitis rates among participating centers, the SCOPE Collaborative proposed a standardized culture method process (or “bundle”) aimed to reduce culture-negative peritonitis rates [8]. This bundle, developed from survey data comparing centers with high vs. low culture-negative peritonitis rates, includes collecting 50 ml of peritoneal effluent, inoculation of effluent into culture bottles, centrifuging and re-suspending the effluent sediment, and then plating the re-suspended effluent on agar plates.

Prior to starting our project, all PD patients with suspected peritonitis (based upon symptoms such as cloudy fluid, fever, abdominal pain, and/or vomiting) would present to Cincinnati Children’s Hospital Medical Center (CCHMC) for peritoneal effluent collection. Peritoneal effluent collections were obtained by either a dialysis nurse, a nephrology fellow, or inpatient floor nurse dependent upon arrival. Antibiotic therapy was routinely not initiated prior to peritoneal effluent collection. We observed that no single method for specimen collection existed among providers, as we noted variation in the length of dwell time required prior to collection (especially in those patients who presented with a “dry abdomen”), volume of effluent collected, and collection containers utilized. We also noted variation in the laboratory handling of peritoneal effluent sample sent for cell count and culture, as well as numerous points at which delays within the diagnostic infectious diseases (microbiology) laboratory could affect microorganism viability and therefore impact growth on culture media. We convened a team to evaluate the SCOPE bundle for local implementation but wanted to create a standardized process that could be utilized for all body fluid collections (pericardial, joint, or peritoneal effluent fluid) sent to the CCHMC microbiology laboratory. We began a quality improvement (QI) initiative to optimize our center’s methods for culturing peritoneal effluent, focused on standardizing of our collection process and using an automated bottled culture system that could be utilized for non-peritoneal effluent body fluids as well. Our main objective was to improve culture detection rates.

Methods

Context

This project took place at CCHMC, a free-standing tertiary care children’s hospital with a broad referral base for specialty care. CCHMC has an extensive QI infrastructure, with purposeful coordination of efforts across the system [10]. Projects supported by the institution will typically align with strategic goals and will account for effects within and without the process being redesigned.

Improvement team

We formed a team of stakeholders including representatives from the Diagnostic Infectious Disease Testing Laboratory (DIDTL), microbiology laboratory, inpatient and outpatient PD nursing management and staff, nephrologists, and infectious disease physicians. There was no interdepartmental collaboration prior to this project. We used the model for improvement, including process mapping, failure mode analysis, and generating a key driver diagram to guide our efforts [11, 12]. The quality improvement team met frequently prior to implementation of this project, after every Plan-Do-Study-Act (PDSA) cycle and as needed during the sustain phase.

Patient population

For the purpose of this study, we included patients ≤ 21 years old undergoing chronic PD with tunneled PD catheters who presented as an in- or out-patient for peritoneal effluent collection, between April 2018–March 2019 (pre-intervention) and April 2019–December 2019 (intervention/post-intervention). Exclusion criteria included patients with PD catheters placed following cardiac surgery, those receiving peritoneal dialysis in the neonatal intensive care unit (NICU), and those diagnosed with eosinophilic peritonitis. Finally, repeat collections during the same peritonitis episode were excluded.

Data collection

All PD patients were tracked through an electronic medical record (EMR) registry (Epic Systems Corporation, Madison, WI). For the pre-intervention group, baseline data was obtained by retrospective chart review of patients who were active on the EMR registry at the time of data extraction. Beginning in December 2018, effluent collections were identified using real-time email notification by an enterprise intelligence resource (VigiLanz Corp, Minneapolis, MN). The enterprise intelligence resource was programmed

to send an email to a team member any time a dialysate culture was ordered and when the PD white blood cell (WBC) count was $\geq 100/\text{mm}^3$.

Data extracted included patient demographics (such as primary kidney disorder, age, gender, ethnicity), date of PD catheter and gastrostomy tube (if applicable) insertions, date of effluent collection, cell count and peritoneal effluent culture results, and other time points relevant to our process measure. Data regarding PD catheter characteristics (such as number of cuffs, tunnel orientation, and exit site orientation of the PD catheter) were unable to be reliably obtained from the medical record and were not included in our extraction.

Interventions

Key drivers of PD effluent culture collection and laboratory processing and planned interventions for process standardization were identified (Supplementary Fig. 1). Our primary intervention was to inoculate peritoneal effluent into pediatric culture bottles directly at bedside by the PD staff (dialysis nurse or nephrology fellow) and incubate specimens using BacT/Alert® Virtuo® Microbial Detection System (bioMerieux, Marcy l'Etoile, France). After 5 ml of effluent was withdrawn from the PD catheter and wasted (to remove any peritoneal effluent filling the dead space of the PD catheter), additional peritoneal effluent was obtained from the PD catheter and inoculated at bedside into culture bottles with effluent volumes as per the package insert recommendations; an additional sample was placed in an EDTA-containing sterile container for cell count and Gram stain. Additional interventions included:

1. Standardizing the use of a last fill for all chronic CCHMC PD patients to prevent “dry abdomen” (defined as having less than 21 ml of peritoneal effluent, the minimum amount of effluent required to properly complete our center’s newly defined collection process) at the time of collection or instilling dialysate with a minimum 1-h incubation before collection in the setting of a dry abdomen. Effluent collection from dialysate bags was discouraged to maintain a standardized collection process.
2. We made a PD cart easily accessible that contained pre-packaged peritoneal effluent collections kits as well as picture cards that clearly outlined each step of peritoneal effluent collection.
3. Initial training and re-education were conducted at various time points during the study for dialysis and lab personnel (PDSA cycle 2).
4. A standard note for documentation in the EMR was created for ease of documentation, though this was not made available until the sustain phase of the study.

All interventions were designed to influence key drivers and were tested using PDSA cycles. When process compliance was thought to be satisfactory, we entered the sustain phase and continued to monitor collections and peritonitis events.

Measures

Our process measure was the total laboratory processing time, defined as the time in minutes from peritoneal fluid collection (inoculation of effluent into the appropriate containers) to (a) time of Gram stain report (pre-intervention) or (b) time to placement of specimen in the BacT/Alert® Virtuo® Microbial Detection System (intervention/post-intervention) with a goal of < 60 min. Time to Gram stain report was used pre-intervention as a surrogate for time to agar plating of the PD effluent for bacterial culture, since the Virtuo® culture system was not implemented prior to the intervention phase.

Process times were recorded to establish our baseline prior to the project initiation from a convenience sample of 16 of the 43 collections which included six peritonitis episodes and 10 from those without peritonitis (one of every five collections). Time points were extracted from the EMR retrospectively during the intervention/post-intervention phases. Our outcome measure was the rate of culture-positive dialysate cultures among patients with PD-associated peritonitis. For PD-associated infectious peritonitis and culture-negative peritonitis, we used definitions as published by the International Society of Peritoneal Dialysis (ISPD) [4, 5]. Our outcome measure goal was peritoneal effluent culture positivity rate of $\geq 85\%$.

Analysis

Statistical analysis was performed using RStudio (RStudio Team [2016], Integrated Development for R. RStudio, Inc., <http://www.rstudio.com/>). Categorical variables were compared using chi-squared or Fisher’s exact tests, and the 2-sample *t*-test was used for continuous variables. A $p \leq 0.05$ (2-tailed) was considered to be statistically significant. Process time was considered as a continuous variable and was tracked using individual (X-) and moving range (MR) charts [13]. Baseline centerline (mean) was calculated using all pre-intervention data points. We defined special cause as eight or more consecutive points above or below the mean [13] that were used to recalculate the centerline. Due to small sample size, high number of predictor variables (measured and unmeasured interventions), and infrequent outcome (peritonitis), we did not perform statistical analysis for peritonitis episode occurrence.

Ethical considerations

As a quality improvement project, this study was exempt from CCHMC institutional review board approval. This project is in compliance with the Standards for Quality Improvement Reporting Excellence (SQUIRE 2.0) guidelines (Supplementary material 2) [14].

Results

Patient demographics

The median age in the intervention group was younger than that of the pre-intervention group (Table 1). Median time between the PD catheter placement to time of peritoneal effluent collection was longer in the intervention group [pre-intervention 97 (IQR 41–344.5) days; intervention/post-intervention 470 (IQR 229–945) days, $p=0.001$]. Baseline characteristics of the two groups are listed in Table 1.

Pre-intervention

There were 16 peritoneal effluent collections with recorded process times among 11 patients (Table 1). The median process time (time from collection to Gram stain report) was 83 min (IQR 53.5–97.8 min). Six peritonitis events occurred in five unique patients, five of which were culture-negative, giving a culture-positive rate of 16.7% (Table 2). There were 3 episodes of culture-positive peritonitis in the pre-intervention group for whom we could not identify process times, and thus were excluded from our study.

Interventions

Thirty collections were obtained from fourteen patients during the intervention/post-intervention phases. Median process time decreased from 83 min (IQR 53.5–97.8) pre-intervention ($n=16$) to 53 min (IQR 36–69.8) during intervention ($n=30$).

Table 1 Baseline characteristics for the patients in the pre-intervention and intervention groups

	Pre-intervention	Intervention	<i>P</i> value
Number of effluent collections with recorded process time	16	30	
Number of unique patients who underwent effluent collection	11	14	
Age at time of collection (years)—median (IQR)	11.28 (6.2–16.72)	3.1 (1.5–8.9)	0.001
Male sex, <i>n</i> (%)	7/11	8/14 (57.1%)	0.74
Ethnicity			
	Caucasian 9/11	11/14	0.84
	African American 2	1/14	
	Other 0	2/14	
Primary kidney disorders			
	Congenital kidney and urinary tract disorders 4	6	0.74
	•Dysplasia with or without obstructive uropathy 3	6	
	•Cystic kidney disease 1	0	
	Glomerular disease 4	2	0.20
	•Congenital nephrotic syndrome 1	1	
	•Focal segmental glomerulosclerosis 3	1	
	Other 3	6	0.42
	•Malignancy 1	0	
	•Failed allograft 2	1	
	•Unknown 0	5	
G-tube present at time of collection, <i>n</i> (%)	6/11 (54.5%)	4/14 (28.9%)	0.18
G-tube placement after PD catheter placement, <i>n</i> (%)	3/6 (50%)	1/4 (25%)	0.43
History of PD catheter replacement prior to peritoneal effluent collection	7/11 (63.6%)	4/14 (28.6%)	0.08
Days from catheter placement to collection—median (IQR)	97 (41–344.5)	470 (229–945)	0.001

IQR interquartile range, PD peritoneal dialysis

Table 2 Peritonitis (total and culture-positive) episodes that occurred during the pre- ($n=6$) and intervention/post-intervention ($n=11$) time periods

	No. of peritonitis episodes	No. of peritonitis events with positive cultures
Pre-intervention	6	1 (16.7%)
Intervention/post-intervention phase		
PDSA cycle 1	0	0
PDSA cycle 2	2	2
Sustain phase	9	9
Total intervention/post-intervention	11	11 (100%)

Increased variability was noted in our system during PDSA cycle 1 (Fig. 1A). This was demonstrated by having two points (4/22/19 and 5/6/19) in the outer 1/3 of the control limits, as well as having special cause on the MR chart with an outlier above the upper control limits (UCL; Fig. 1B). A centerline shift occurred concurrently with a decrease in the UCL on both the X- and MR-charts, indicative that the process became more reliable (Fig. 1). Finally, an outlier was noted on the sustain phase on both the X- (Fig. 1B) and MR-charts (Fig. 1A). These two outliers reflected delays in receiving the effluent samples after collection.

Among the 30 intervention/post-intervention PD effluent collections with recorded process times, 11 episodes of peritonitis occurred, and all had positive cultures. Our PD culture positivity rate increased from 16.7% pre-intervention ($n=6$) to 100% post-intervention ($n=11$) (Table 2). Three episodes of culture-positive peritonitis did not have process times and thus were excluded from this study. There was no predominant causative organism among either study group (Table 3). Lastly, there were no cases of PD-associated peritonitis in the 6 months during the sustain phase of this QI project from March to October 2020.

Discussion

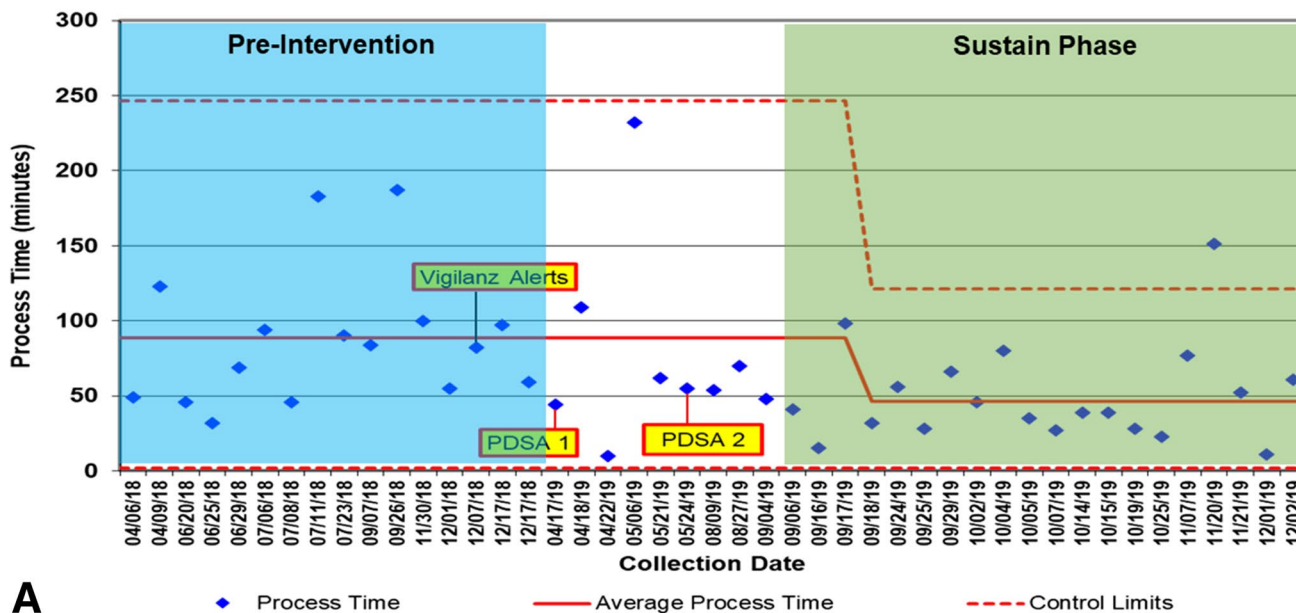
In this study, we demonstrated an improvement of our median PD culture process time to below 60 min and improved our PD culture positivity rate of 16.7 to 100% that occurred following standardizing of our collection process and the utilization of an automated bottled culture system. This shift in the median process time occurred in conjunction with an increase in process reliability (Fig. 1), and more accurately reflects the time to placement of effluent into optimal growth conditions than time to Gram stain report. There were no cases of PD-associated infectious peritonitis for 6 months (March–October 2020) during the sustain phase of our QI project, which overlapped with initiation of lockdowns due to the COVID-19 pandemic. Although

interesting, our study was not directly aimed at preventing culture-positive peritonitis.

Improvement science has been used successfully in decreasing peritonitis rates among children by standardizing protocols and reducing practice variation [2], and it is thus not surprising that similar methods may be used for reducing culture-negative peritonitis rates. While Davis et al. reported high culture-negative peritonitis rates among surveyed centers, an association with peritoneal effluent collection and/or laboratory processing methods was not reported [9]. Based on published evidence, we hypothesized that process measures were responsible for our high rate of culture-negative peritonitis. We therefore designed our interventions to address several known modifiable risk factors such as avoiding pre-culture administration of antibiotics, ensuring adequate dwell time prior to sample collection, and obtaining sufficient sample volume for culture. Although not in published evidence, we further hypothesized that delays in the laboratory could cause falsely negative culture results and we aimed to decrease the laboratory processing time of peritoneal effluent collections to less than 60 min. Our results support both hypotheses, indicating improvement in process measures alone could mitigate risk of culture-negative peritonitis. However, this should be validated by a multicenter study.

Because this project involved multiple hospital systems (inpatient care, outpatient care, dialysis, infectious disease diagnostic laboratory), we wished to create a standardized procedure for specimen collection and laboratory processing applicable to all body fluids (peritoneal effluent, as well as pericardial and joint body fluid) submitted to our Diagnostic ID testing laboratory. Our process therefore deviated from the proposed SCOPE bundle (as we did not centrifuge and resuspend PD sediment or place the resuspended fluid directly on agar plates for culture), and thus our results cannot evaluate the effectiveness of the SCOPE bundle. Nonetheless, our culture collection and methodology remained within that recommended by the Infectious Disease Society of America [15] and ISPD [5], and greatly simplified the process for lab staff. Our use of the BacT/Alert® Virtuo® Microbial Detection System is within its

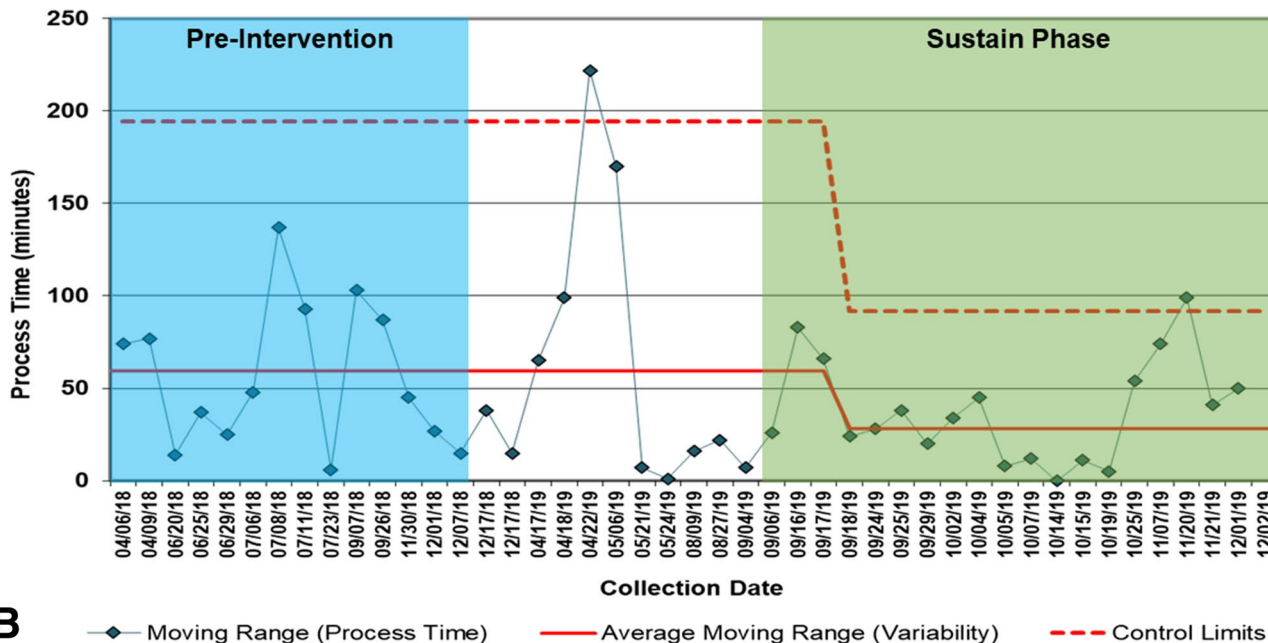
Process Time for Peritoneal dialysis fluid cultures X-Chart April 2018 - December 2019



A

◆ Process Time — Average Process Time - - - Control Limits

Process Time for Peritoneal dialysis fluid cultures MR-Chart April 2018 - December 2019



B

◆ Moving Range (Process Time) — Average Moving Range (Variability) - - - Control Limits

Fig. 1 Individual (A) and moving range (B) charts showing process time for peritoneal dialysis effluent cultures during the pre-intervention (blue), intervention (white), and sustain/post-intervention (green) phases. The intervention for PDSA cycle 1 was the bedside inoculation of effluent into the appropriate containers and placement into our microbial detection system. The intervention for PDSA cycle 2

was the re-education of the main laboratory staff. A decrease in the average process time during the sustain phase likely more accurately reflects time to placement of effluent into optimal growth conditions. A decrease in the upper control limit also occurred during the sustain phase which reflects that the process became more reliable

Table 3 Causative organisms of infectious peritonitis that occurred during the study periods. There was no predominant organism during any of the study periods

Study group	Causative organisms
Pre-intervention	<i>Pseudomonas aeruginosa</i>
Post-intervention	1. <i>Neisseria mucosa/sicca</i>
	2. <i>Acinetobacter baumannii</i>
	3. <i>Staphylococcus epidermidis</i>
	4. <i>Streptococcus salivarius</i> and <i>Streptococcus parasanguinis</i>
	5. <i>Klebsiella pneumoniae</i>
	6. <i>Eikenella corrodans</i>
	7. <i>Mycobacterium avium-intracellulare</i>
	8. <i>Corynebacterium species</i>
	9. <i>Klebsiella oxytoca</i> and <i>Enterococcus faecalis</i>
	10. <i>Staphylococcus aureus</i>
	11. <i>Klebsiella pneumoniae</i>

US Food and Drug Administration approval, and equivalent ability has been demonstrated to detect Gram positive and Gram negative organisms with sterile body fluids including peritoneal dialysate when compared to traditional agar plating technique [16]. We did not compare our method to more traditional plating methodologies, including those designed to enhance detection [17]. Future studies should evaluate culture yield, costs, and risk of technical error, such as spilling an effluent sample of both methods. Lastly, cost-effectiveness analysis should be performed to compare the use of culture bottles in microbial detection systems, centrifugation for plating and a combination of methods to help identify which method would be ideal, especially in resource-limited settings.

Our success was likely in part due to a number of factors. First, our utilization of the enterprise intelligence resource enabled us to identify infrequent measurement opportunities in real time thus maximizing our assessment and learning. Second, our multidisciplinary collaboration helped connect systems that normally would work in tandem. Our addition of the infectious disease clinicians and Diagnostic ID Testing laboratory staff to nephrologists and PD staff added an outsider's perspective on the process and facilitated a common understanding of the process as a whole. This enabled development of a comprehensive intervention plan aimed to incorporate the expertise of all healthcare personnel involved in the process of peritoneal effluent collection and processing.

Our study is subject to a number of limitations. The small sample size of peritonitis and collections limited our ability to draw statistical inferences regarding if a true difference in culture-negative peritonitis existed. However, the purpose of this QI project was to improve our local culture effluent collection process, rather than affect our culture-negative

peritonitis rate. Our process analysis showed a true improvement following our intervention, which appears to have been associated with an improvement in culture positivity. Further study, with a more robust sample size, is necessary to address this important question. Our use of a convenience sample for baseline measurement may not have yielded a representative value of our true baseline process. However, assuming process time influences culture positivity, using all peritonitis episodes with recorded process times (6 of the 9), only one of which was positive, may have biased our sample toward the null. It is reasonable to assume that including more non-peritonitis collections would not inform our hypothesis of culture positivity being associated with time to culture when peritonitis is present and would not affect our conclusions. By using different process definitions pre- (time to Gram stain report) and post-intervention (time to placement into Virtuo® system), we may have introduced a measurement bias. Our intent was to measure time to optimal growth conditions. By using Gram stain report, we likely overestimated pre-intervention time assuming most lab technologists would read and report a Gram stain after inoculating plates. However, our post-intervention measure likely represents a more accurate time to optimal growth conditions and can be used for benchmarking future improvement efforts. As in any quality improvement project, context likely played a significant role in our success [18]. Our institution has a strong emphasis on safety culture, quality transformation is embedded in its framework, and this project was supported by institutional QI infrastructure [10]. Our measurement of time points could also be susceptible to the Hawthorne effect, where staff tried to move more quickly at the project's start [19]. However, process times remained lower throughout the project, suggesting the change was more intrinsic to the system. Finally, ours is a single-center observational study, and our results may not be generalizable to all contexts.

In conclusion, an improvement in process time and culture positivity rate occurred following standardization of our PD fluid culture process and utilization of an automated blood culture system for the evaluation of suspected peritonitis in a pediatric peritoneal dialysis population. The next steps will include sustaining the measures implemented and monitoring for increases in the culture-negative peritonitis rate. Future studies should investigate the effect of collection and processing methods on culture yield to better elucidate key factors that contribute to culture-negative peritonitis, and to validate that process standardization may be useful in improvement of effluent culture detection rates in a multicenter study.

Supplementary Information The online version contains supplementary material including a Graphical Abstract available at <https://doi.org/10.1007/s00467-022-05533-1>.

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Author contribution All authors contributed to the development of this quality improvement project and publication. Material preparation, data collection, and analysis were performed by Scott Pangonis, and results were reviewed by Joel Mortensen, Joshua K. Schaffzin, Edward Nehus, and Donna Claes. The first draft of the manuscript was written by Scott Pangonis, MD, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Declarations

Conflict of interest The authors declare no competing interests.

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