

Early Detection of Peritonitis Using Effluent Analysis



Disclosures

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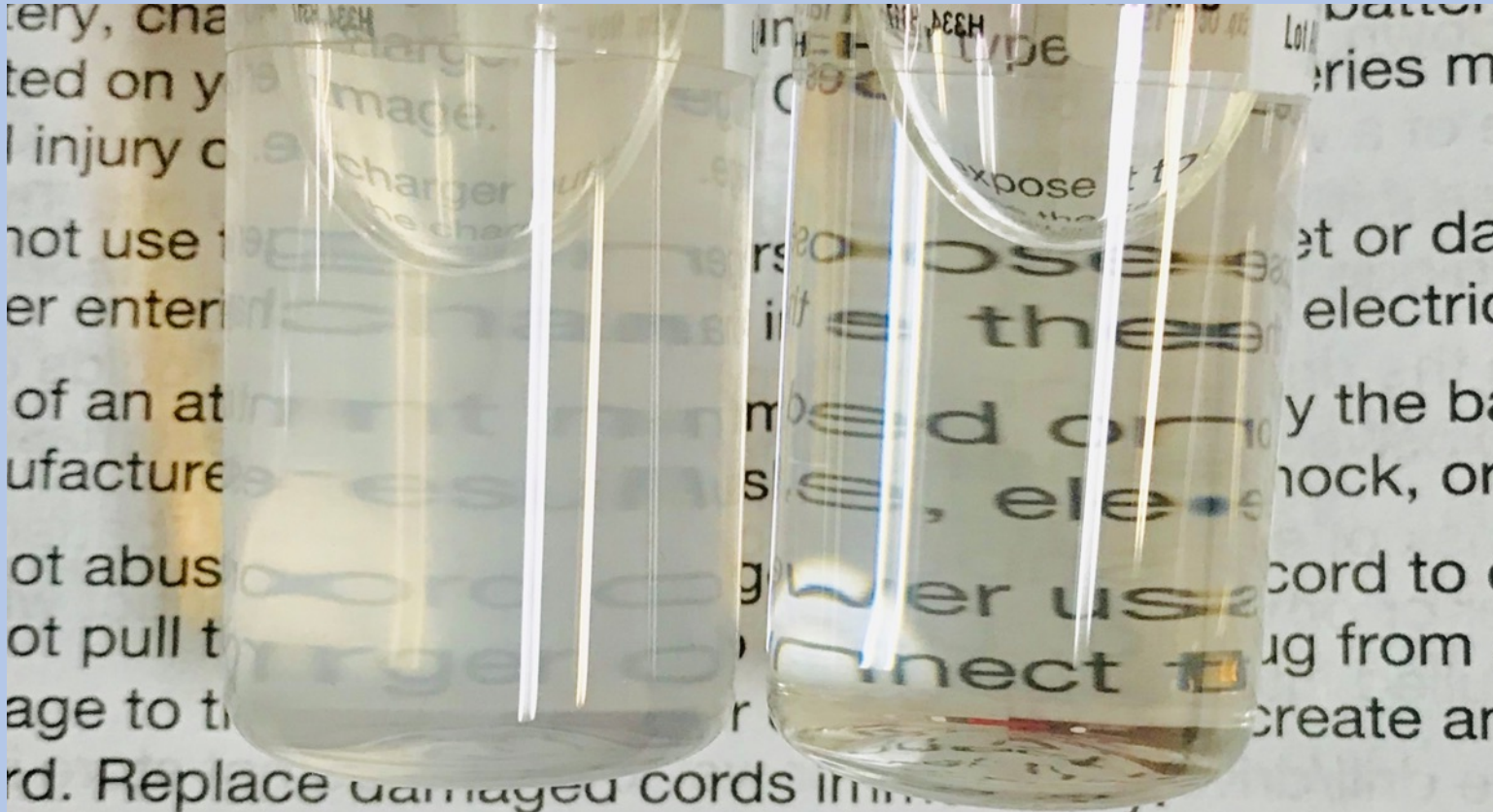
Coordinated Kidney Care Group

Kittanning, PA

PI in CATCH and ACT studies

Disclosures: None

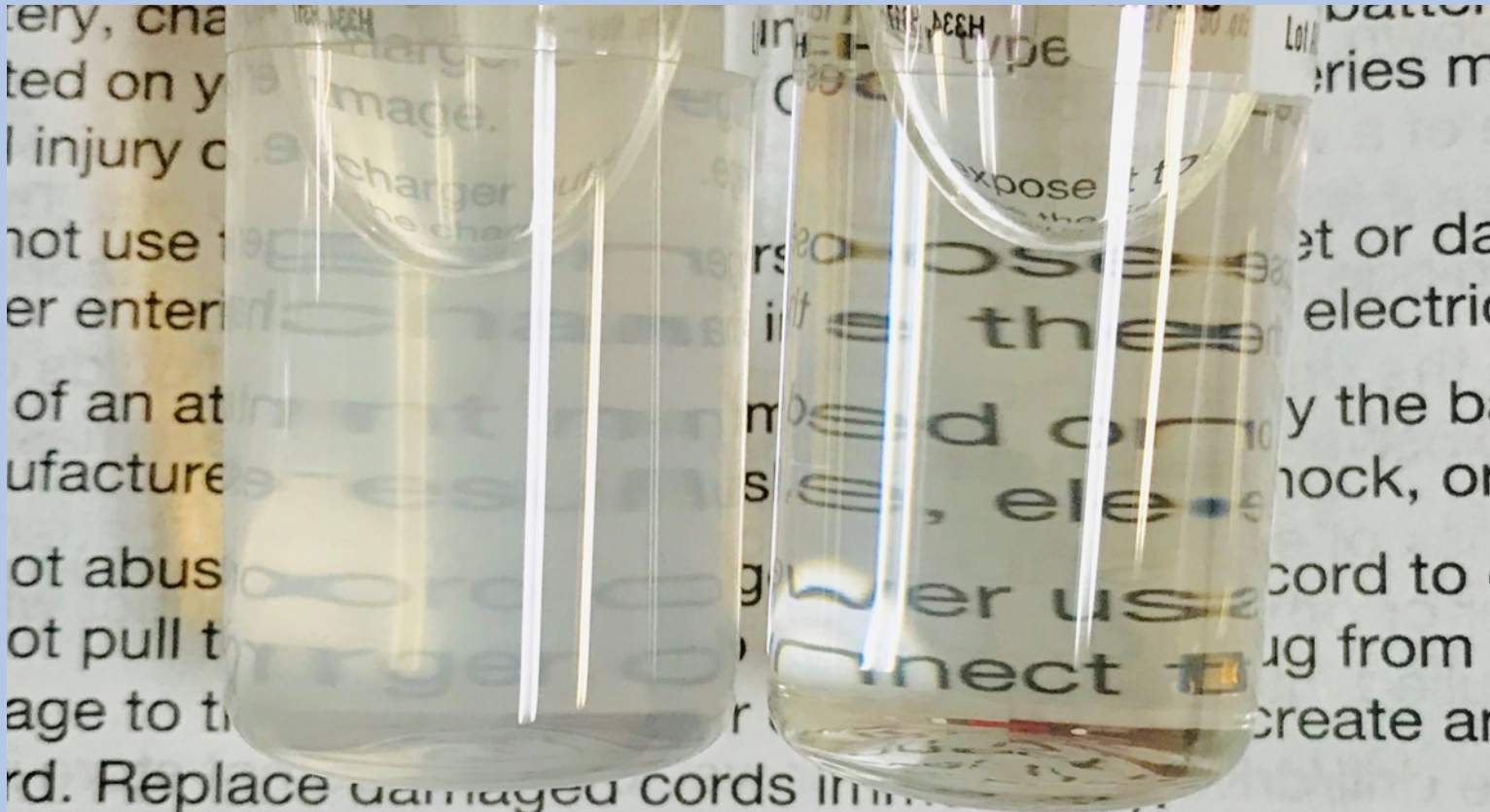
Which Sample is representative of Peritonitis?



Which Sample is representative of Peritonitis?

BOTH samples are at peritonitis levels defined by the International Society of Peritoneal Dialysis (ISPD) threshold of > 100 WBC/ μ l

⇒ Visual inspection of fluid cloudiness by the “newspaper” test is insufficient. Effluent analysis can enable earlier identification of peritonitis onset.

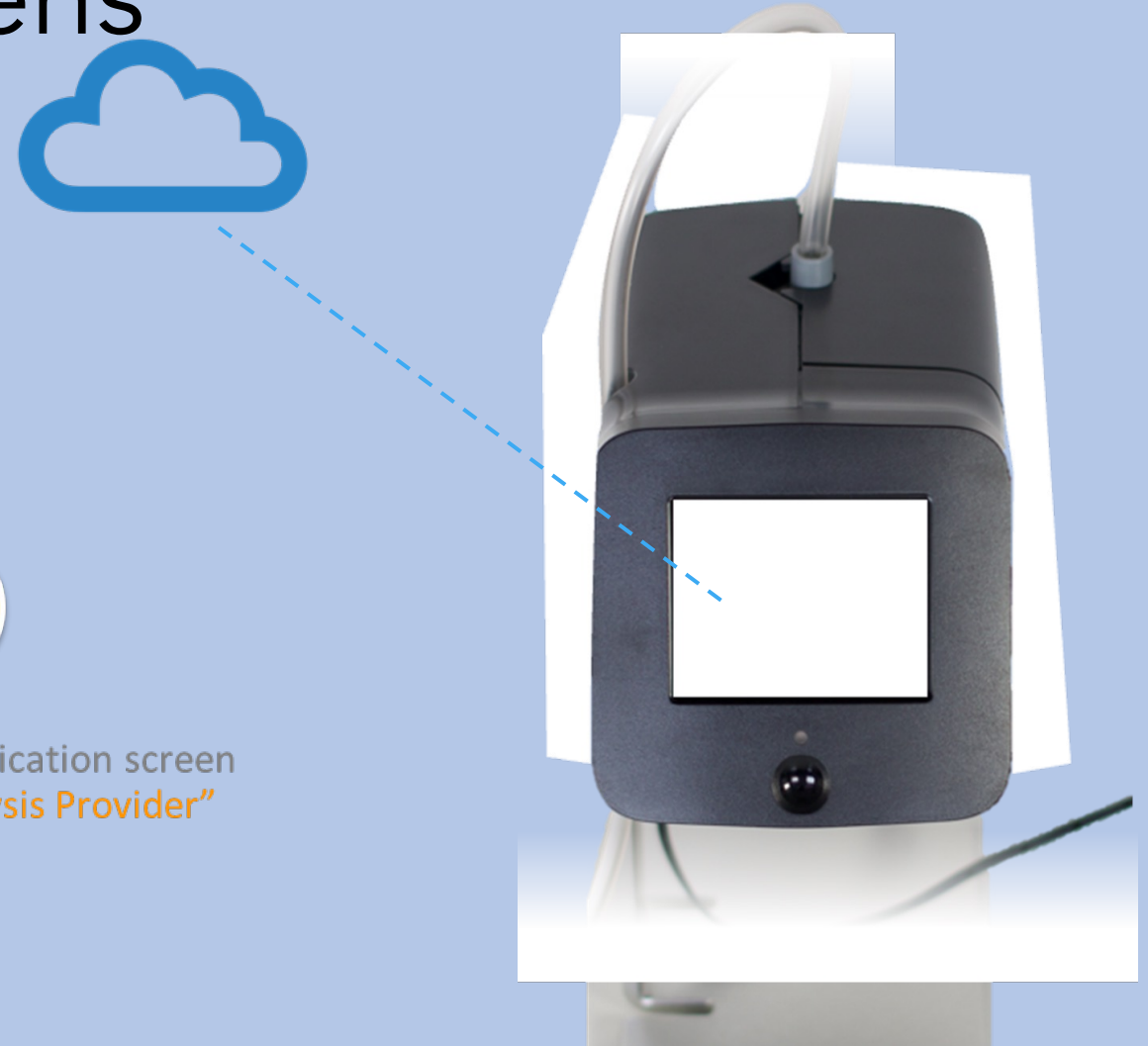
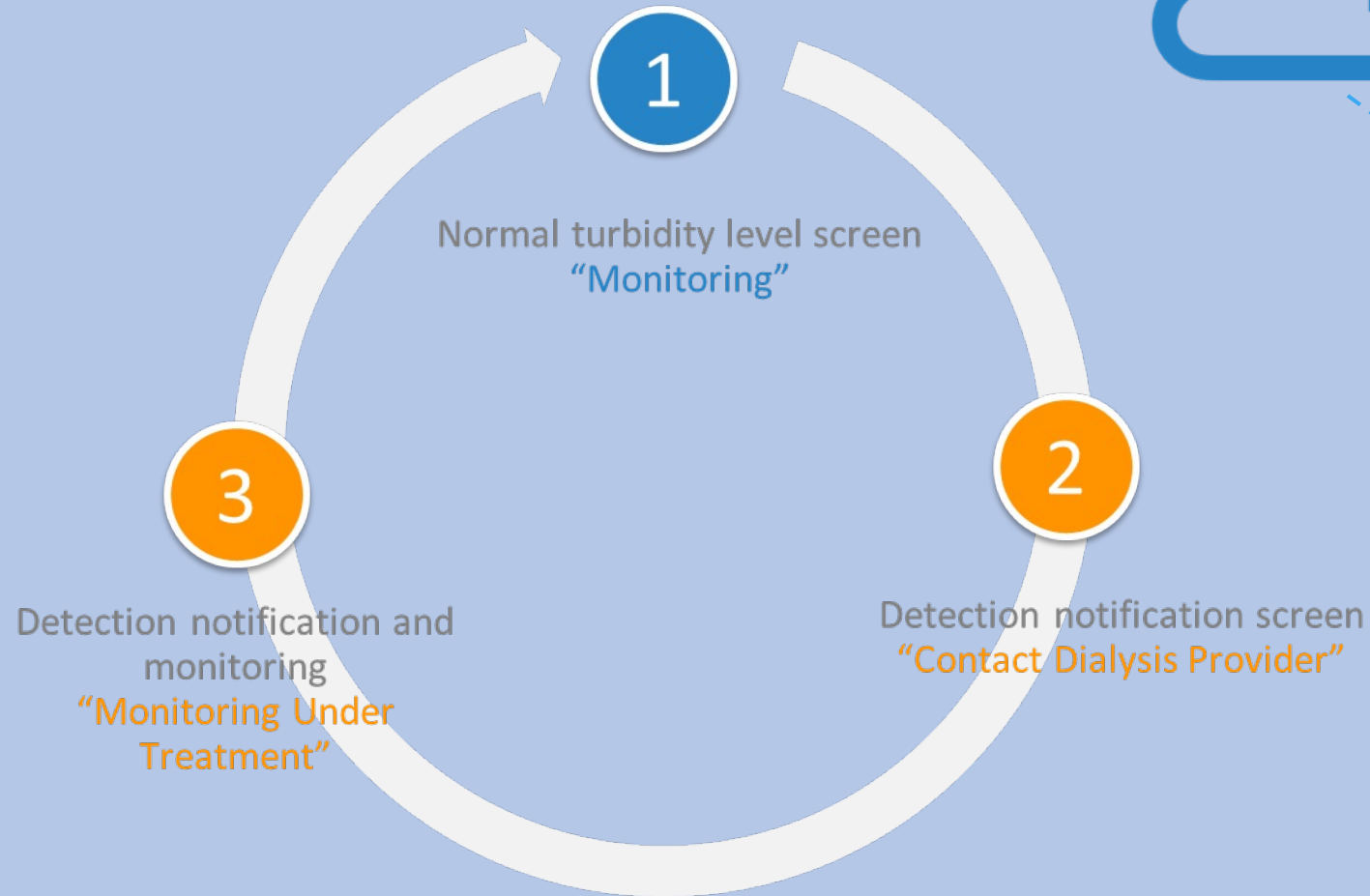


Cloudcath Set-Up with Cyclor

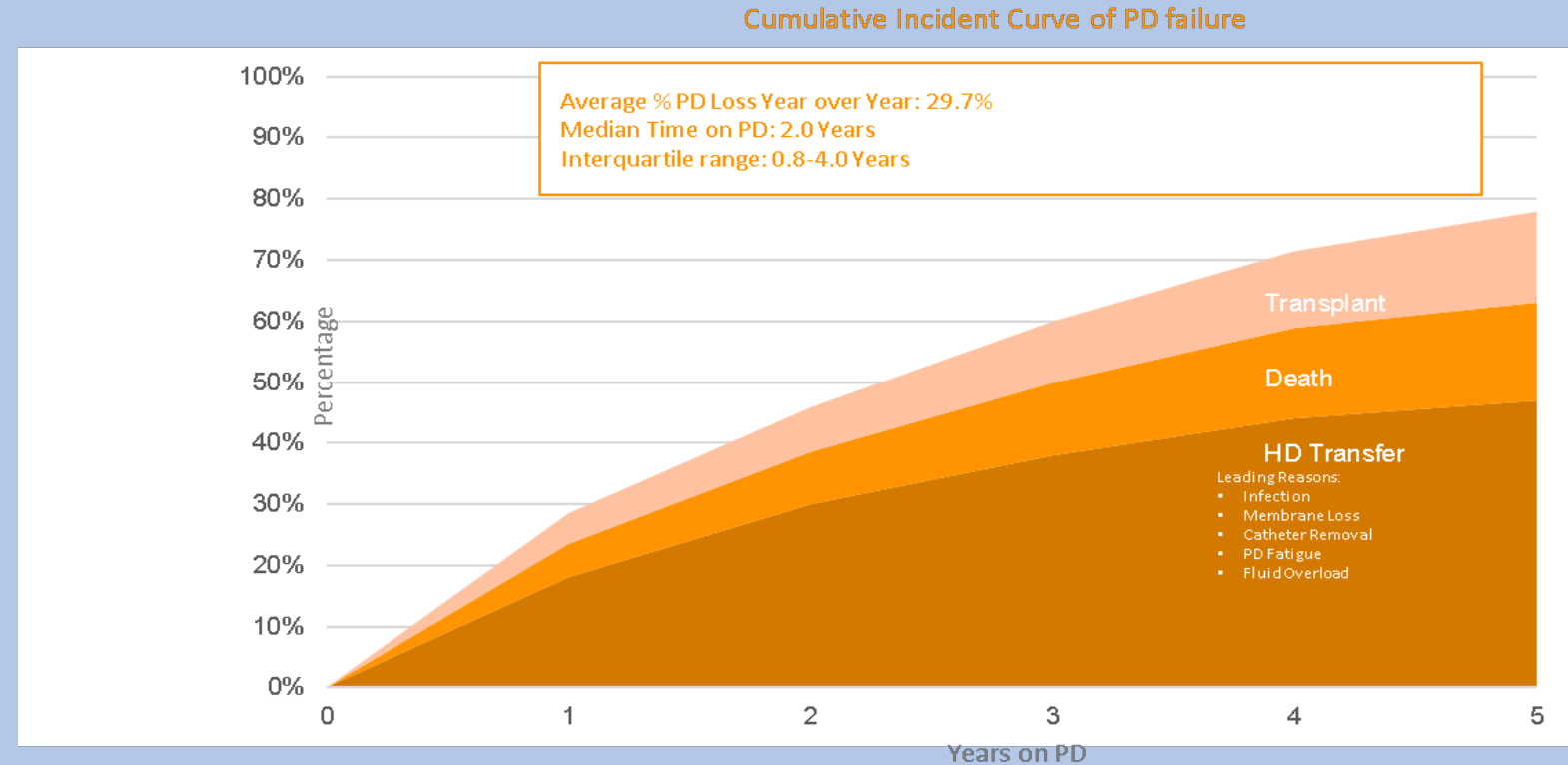


Compatible with Baxter and Fresenius PD Cyclers

Optimized Usability 3 Simple Status Screens

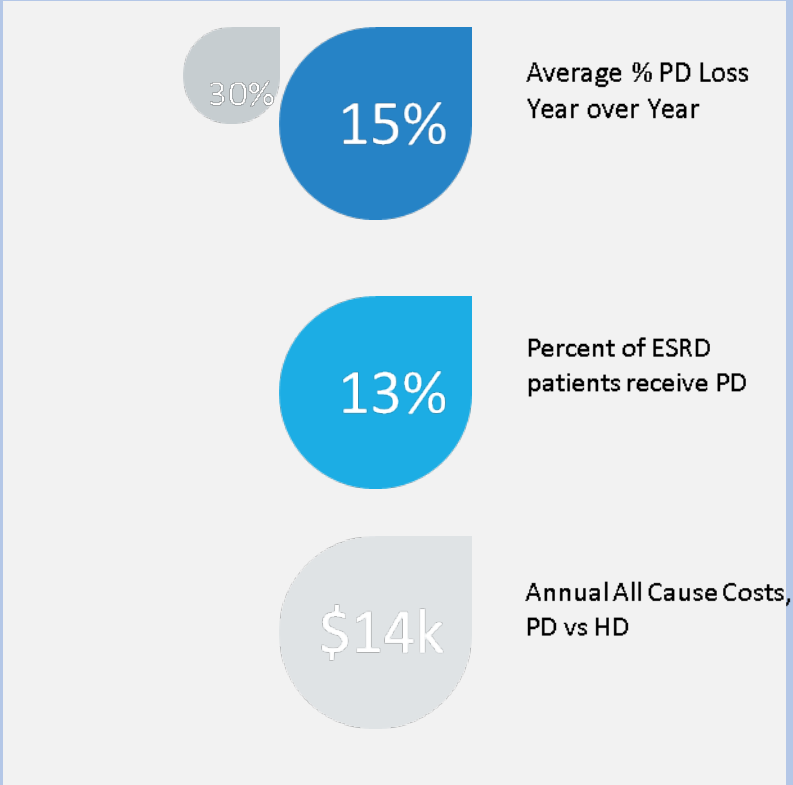
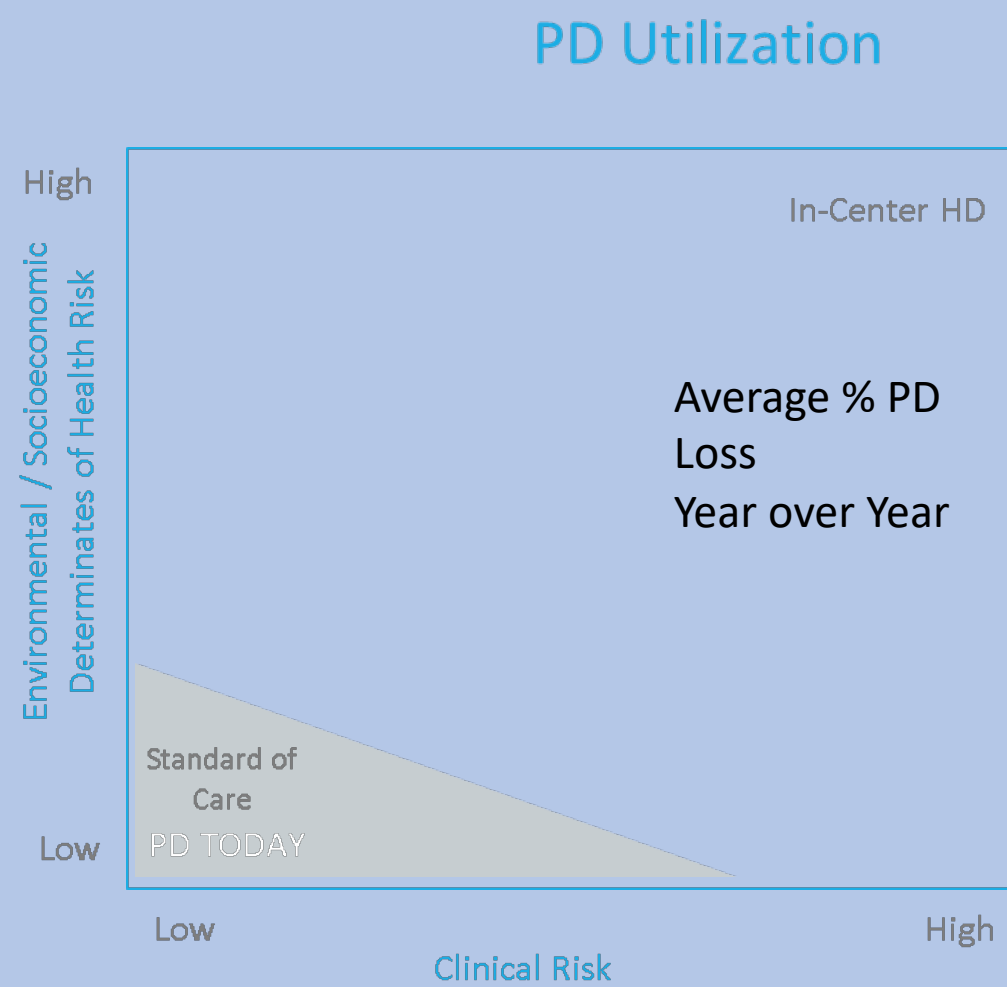


Reducing PD Drop Out



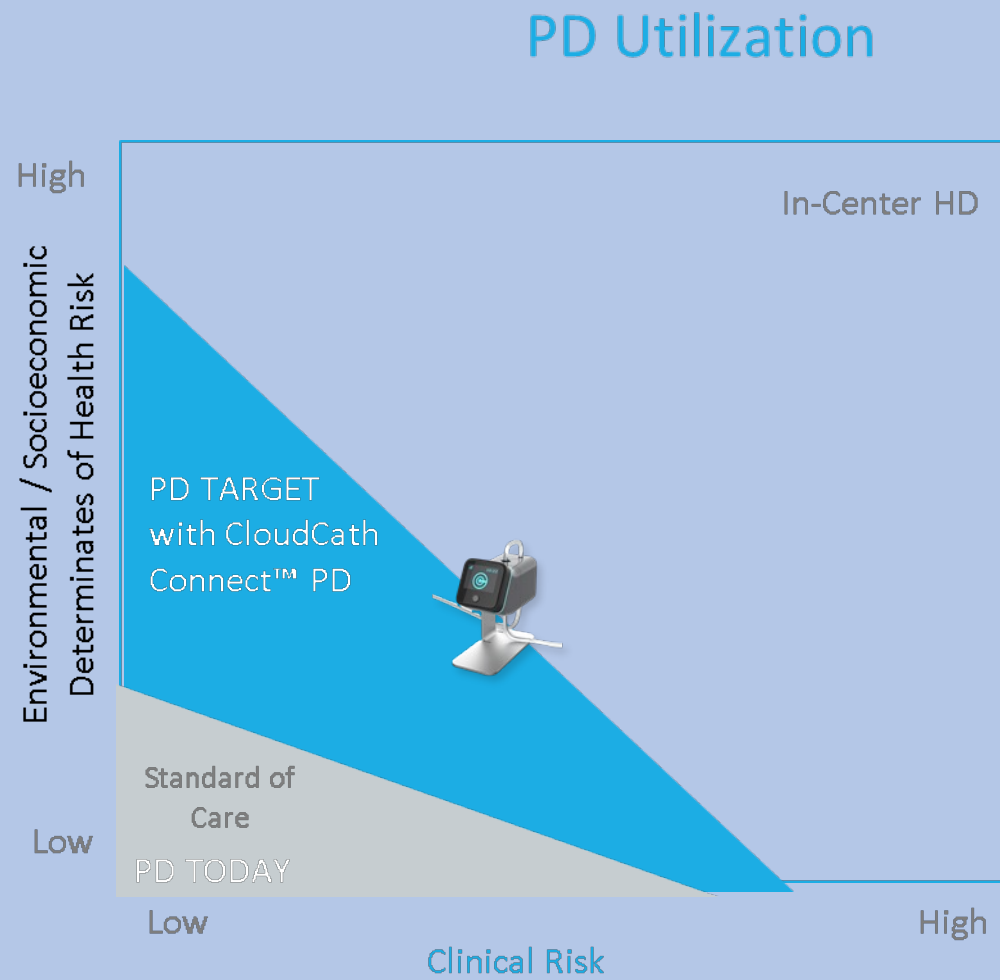
Variation in Peritoneal Dialysis Time on Therapy by Country
Results from the Peritoneal Dialysis Outcomes and Practice Patterns Study
Mark Lambie, et. al. and the PDOPPS Steering Committee
CJASN June 2022, 17 (6) 861-871; DOI: <https://doi.org/10.2215/CJN.16341221>

Increase PD Utilization

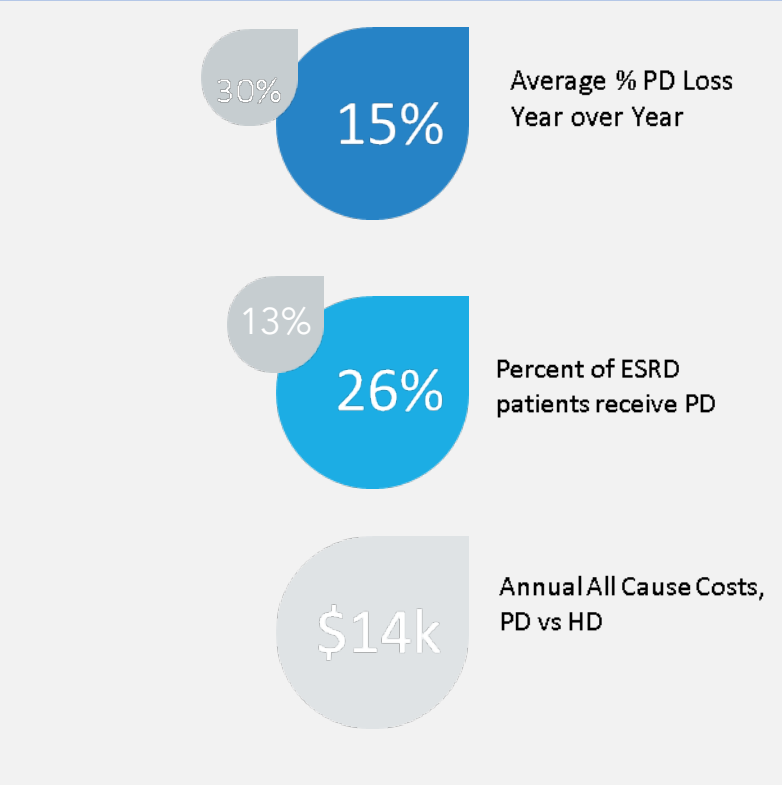


2021 Annual Report from USRDS, End Stage Renal Disease: Chapter 2, Home Dialysis, Figure 2.1a
Utilization of home dialysis, overall and by modality, stratified by ESRD status, 2009-2019

Increase PD Utilization



2021 Annual Report from USRDS, End Stage Renal Disease: Chapter 2, Home Dialysis, Figure 2.1a
Utilization of home dialysis, overall and by modality, stratified by ESRD status, 2009-2019



CloudCath Connect™ PD Studies

Early detection of infection relative to standard of care, sensitivity/specificity, and improvement of outcomes with use

CloudCath Connect™ PD | Studies



A Prospective Clinical Study of the
Ability of the CloudCath System to
Detect Peritonitis During In-home PD

262 enrolled patients | 18 sites

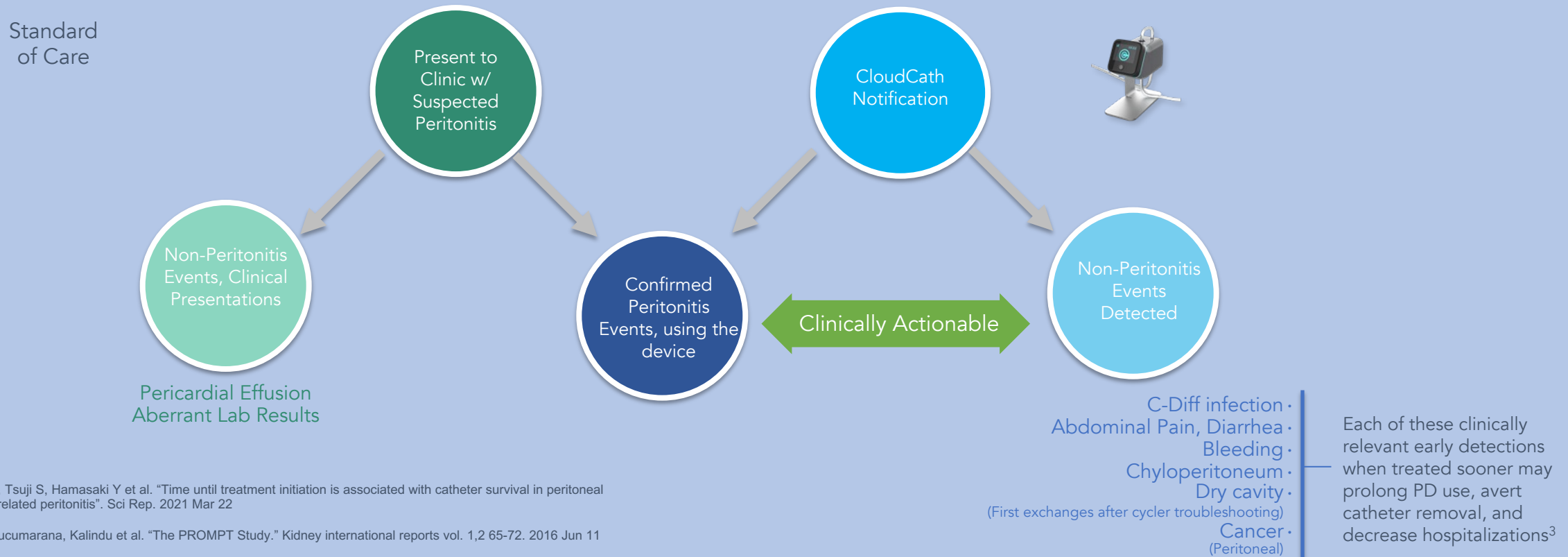
- Evaluates how much earlier the system can detect the onset of peritonitis and other clinically actionable events compared to the standard of care (*visibly cloudy effluent or the presentation with signs and symptoms*)
- The notification capability of the CloudCath System is **deactivated** so that neither Study Participants nor Study Investigators are aware of the device measurements

<https://clinicaltrials.gov/ct2/show/NCT04515498>

CATCH Study | Actionable Notices

Hours matter when it comes to treating peritonitis

Delay in treating peritonitis is associated with a significantly higher catheter removal rate (16% vs. 38%)¹ and an increased risk of PD failure and death by 7%² for each hour of delay.



1. Oki R, Tsuji S, Hamasaki Y et al. "Time until treatment initiation is associated with catheter survival in peritoneal dialysis-related peritonitis". Sci Rep. 2021 Mar 22

2. Muthucumarana, Kalindu et al. "The PROMPT Study." Kidney international reports vol. 1,2 65-72. 2016 Jun 11

3. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5678844/>

Results

Interim analysis as of June 30, 2021, the CloudCath system has been used by:

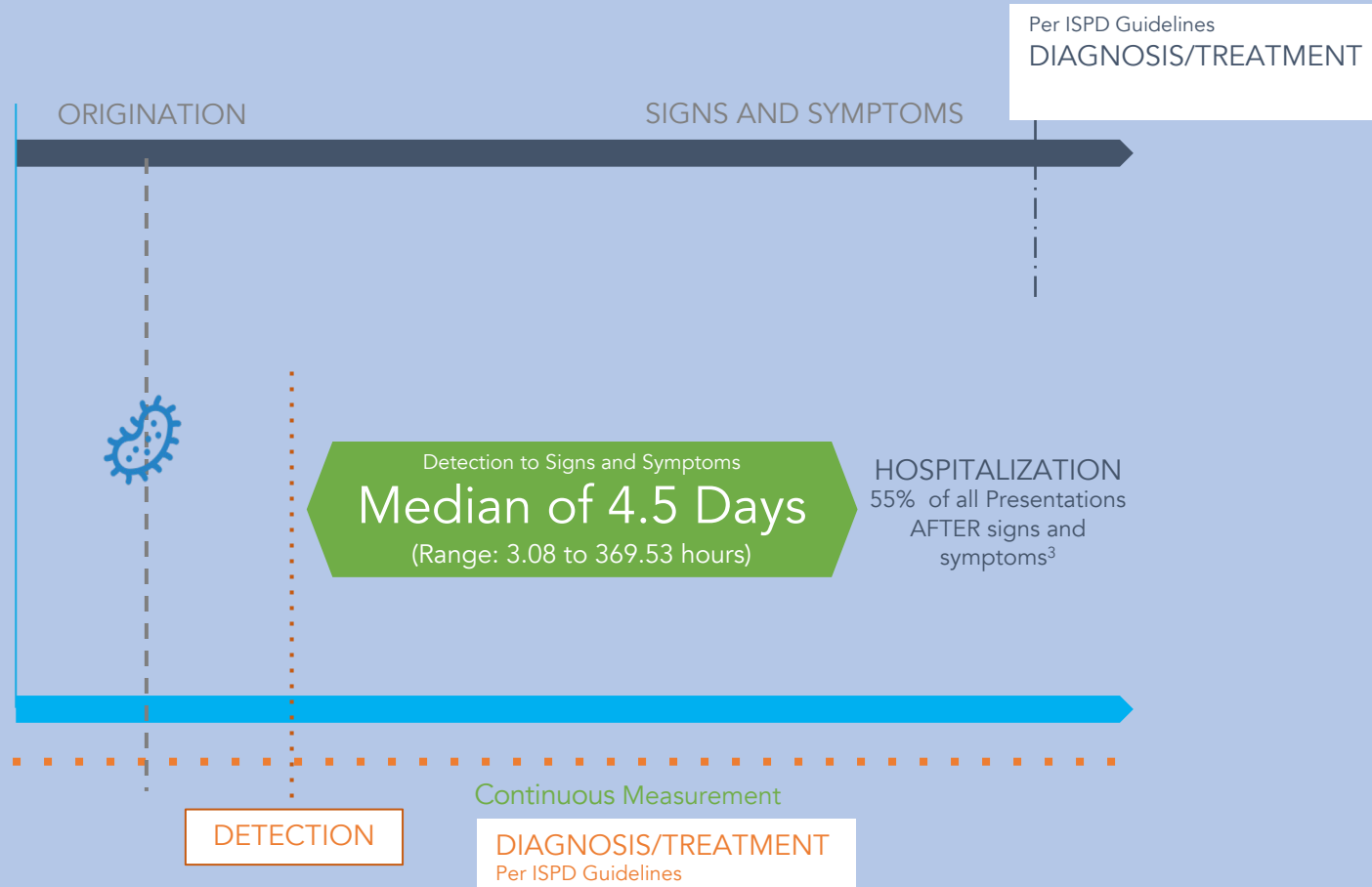
- 185 participants for a total of 26,185 days (71.7 participant years) and had analyzed 126,300 individual PD exchange cycles.
- A total of 28 participants presented to the clinic/hospital with 34 potential peritonitis events.
- 22 participants who experienced 26 peritonitis events that met ISPD criteria (>100 WBC/ μ l and $> 50\%$ PMN)
- 7 participants who experienced 8 events that did not meet ISPD criteria and 1 participant who experienced both.
- The median time from when the CloudCath system detected changes in turbidity scores to the time in which the participant presented to Clinic/hospital was 4.5 days, (range <0.2 to 15.4).
- P value <0.0001 Calculated using Wilcoxon Signed Rank Test.

Participant ID	Event Number	Time from CloudCath System Detection of Changes in Turbidity Scores per CloudCath System to Clinic/Hospital Presentation for Peritonitis (Hours)
1001-03	1	223.08
1002-02	1	27.92
1002-04	1	320.17
1003-03	1	33.12
	2	N/A ^A
1003-04	1	N/A ^B
1003-11	1	N/A ^B
1004-04	1	106.1
1004-06	1	3.08
1004-07	1	51.97
1004-08	1	369.53
1005-08	1	106.02
1006-01	1	N/A ^B
1006-05	1	297.63
	2	N/A ^B
	3	8.88
1006-12	1	N/A ^B
1008-08	1	279.43
1008-11	1	61.28
1008-17	1	8.27
1012-03	1	N/A ^A
1012-08	1	N/A ^A
	2	225.12
1012-13	2	108.35
1013-03	1	182.17
1015-05	1	118.73
Mean \pm SD, (N): 142.64 \pm 122.24 hours, (17)		
Median (Min, Max): 108.35 hours (3.08, 369.53)		

A: Not applicable as CloudCath System CloudCath System was not used for 14 days in advance of presentation or date/time effluent lab draw meeting ISPD criteria, whichever was earlier.
B: Unable to calculate as CloudCath System turbidity score did not meet algorithm.

Catch Study- Early Detection

Standard
of Care



Results- "False Positives"

- C-Diff Infection
- Abdominal Pain, Diarrhea
- Bleeding
- Chyloperitoneum
- Dry Cavity (First exchange after cycloer troubleshooting)
- Cancer (Peritoneal)

Conclusion

The CATCH study demonstrated that the CloudCath system can:

- detect changes in effluent turbidity scores on average 4.5 days earlier than current standard of care.
- This early detection may prompt evaluation for peritonitis significantly earlier than current standard of care.
- The time gained by the early detection may allow for earlier diagnosis and treatment of peritonitis that may, in turn
- reduce risk of peritonitis-related complications such as :
 - Hospitalizations
 - PD catheter removals
 - permanent transfer to HD
 - Peritoneal membrane failure

**FURTHER STUDIES INCLUDING EARLY
PHYSICIAN NOTIFICATION**

CloudCath Connect™ PD | Studies



ACT Study

A Prospective Clinical Study to
Assess the Clinical Utility of Turbidity
With the CloudCath System

300+ participants | Enrollment Ongoing

- Evaluates the significance of improving patient management (clinical pattern improvement) due to early detection with the device
- The notification capability of the CloudCath System is **activated** for both the participant and healthcare provider so the patient can be diagnosed by their healthcare provider
- Clinical outcomes from the ACT study will be compared to the results of the CATCH study

ACT Study: A Prospective Clinical Study to Assess the Clinical Utility of Turbidity With the CloudCath System

BACKGROUND:

Peritonitis has long been recognized as a leading complication associated with PD¹. Currently, the international standard of care for adult and pediatric patients is outlined in guidelines by the International Society for Peritoneal Dialysis (ISPD)². Standard practice is to advise patients to monitor for signs of infection (abdominal pain, etc.) and to closely watch for signs of cloudy effluent fluid, the newspaper test.

CloudCath developed a continuous monitoring device that pairs with cloud-based software to monitor turbidity in order to detect changes in PD effluent associated with peritonitis.

ACT Study: A Prospective Clinical Study to Assess the Clinical Utility of Turbidity With the CloudCath System

Purpose of the Study

To evaluate the performance of the CloudCath System to detect peritonitis in Study Participants undergoing peritoneal dialysis for ESRD, as compared to standard of care.

Methods

We conducted a single arm, open label, multicenter outpatient study where study participants used the CloudCath system that had the notification capability deactivated so that neither participants nor investigators were aware of the device results.

We measured the time between device detection of turbid fluid and the study participant presentation to the clinic/hospital with signs/symptoms of peritonitis.

PATIENT CASE STUDY

Patient Case Study

- DD is a 64 year old gentleman who has been maintained on Peritoneal Dialysis since 3/12/2019.
- PMHx: HTN, chronic atrial fibrillation and Hidradenitis Suppurativa
- He has been on doxycycline and topical clindamycin for HA. Over one year prior to the study he received Rituxin.

EVENT 1

Patient Case Study-Event 1

- Presented to the dialysis unit on 7/8/22
- DD was asymptomatic, however his device detected changes in turbidity of the fluid
- DD denied any episodes of contamination; although he had some low drain alarms and an episode where the cyclor malfunctioned; requiring a change in the line set up

Initial Cell Count and Culture

Appearance	Colorless
Color	Clear
WBC's	5
RBC's	<1000
Neutrophils	50
Lymphocytes	23
Monocytes	27

Initial Cell Count and Culture

Gram Stain	Negative
Body Fluid Culture	Citrobacter freundii complex
	Providencia rettgeri
	Enterococcus gallinarum
	Pseudomonas seruginosa
	Leclercia adecarboxylata
	Micrococcus species
Anaerobic Culture	No Growth

- Due to the low WBC count and the lack of symptoms, we elected not to treat the patient.
- He did not develop peritonitis.



TURBIDITY MONITORING- EVENT 1

EVENT 2

Patient Case Study-Event 2

- A second turbidity notification was received 9/16/22
- Again DD was asymptomatic, however he noticed cloudy effluent
- DD denied any episodes of contamination; noted several slow drain alerts where repositioning was successful
- We were unable to reach the subject to have him come in for evaluation until 9/19/22 at which time a 3rd turbidity notification was triggered

Initial Cell Count and Culture

	9/19/22
Appearance	Colorless
Color	Clear
WBC's	534
RBC's	<1000
Neutrophils	96
Lymphocytes	3
Monocytes	1

*Initial Culture showed Diptheroids

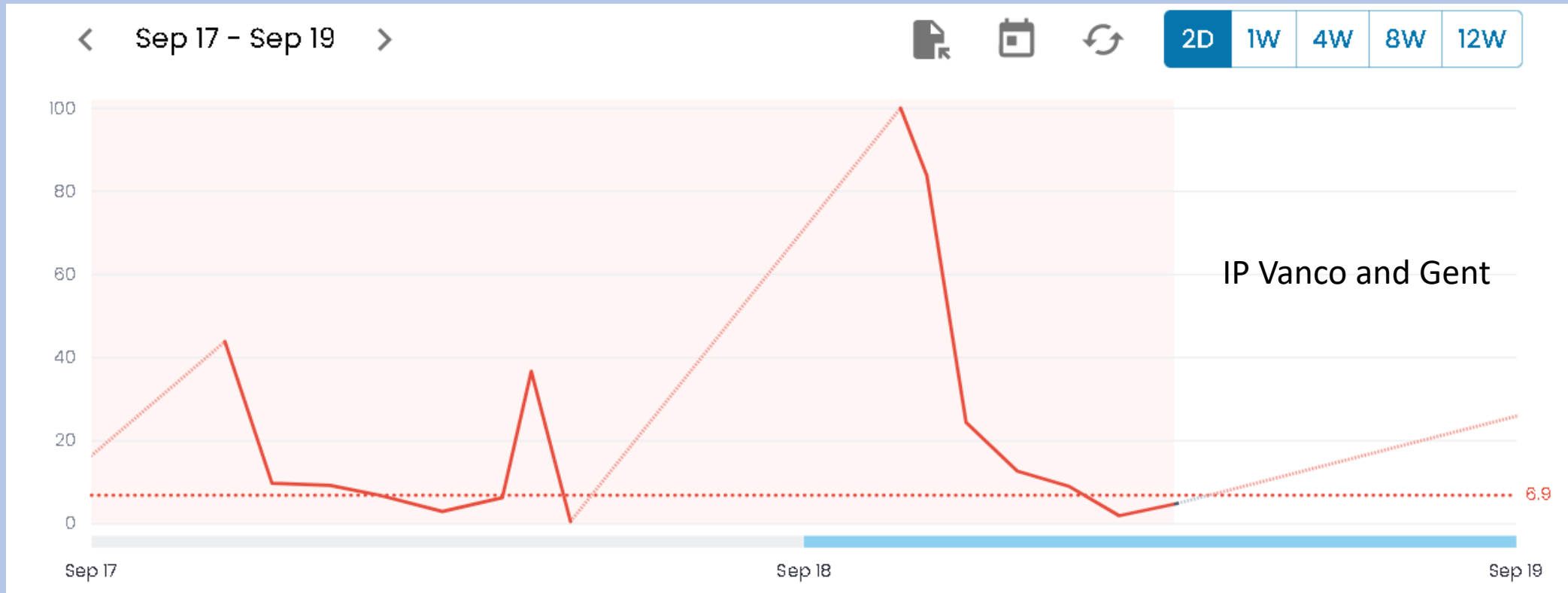
*Gram stain- Rare WBC's

Subsequent Cell Counts

	9/20/22	9/21/22	9/22/22	9/25/22	9/27/22
Appearance	Colorless	Colorless	Colorless	Colorless	Colorless
Color	Hazy	Clear	Clear	Clear	Clear
WBC's	961	134	116	72	104
RBC's	34	15	22	8	5
Neutrophil	84	94	80	98	94
Mononuclear Cells	14	6	18	2	6
Eosinophils	2		2		

*Treated with Vancomycin and Gentamycin

*Additional Cultures drawn 10/5/22 grew *Pseudomonas Aeruginosa*



TURBIDITY MONITORING- EVENT 2

EVENT 3

Event 3

* Due to the recent peritonitis and the pt history of Hidradenitis Suppurativa, the patient developed an exit site infection on 10/5/22

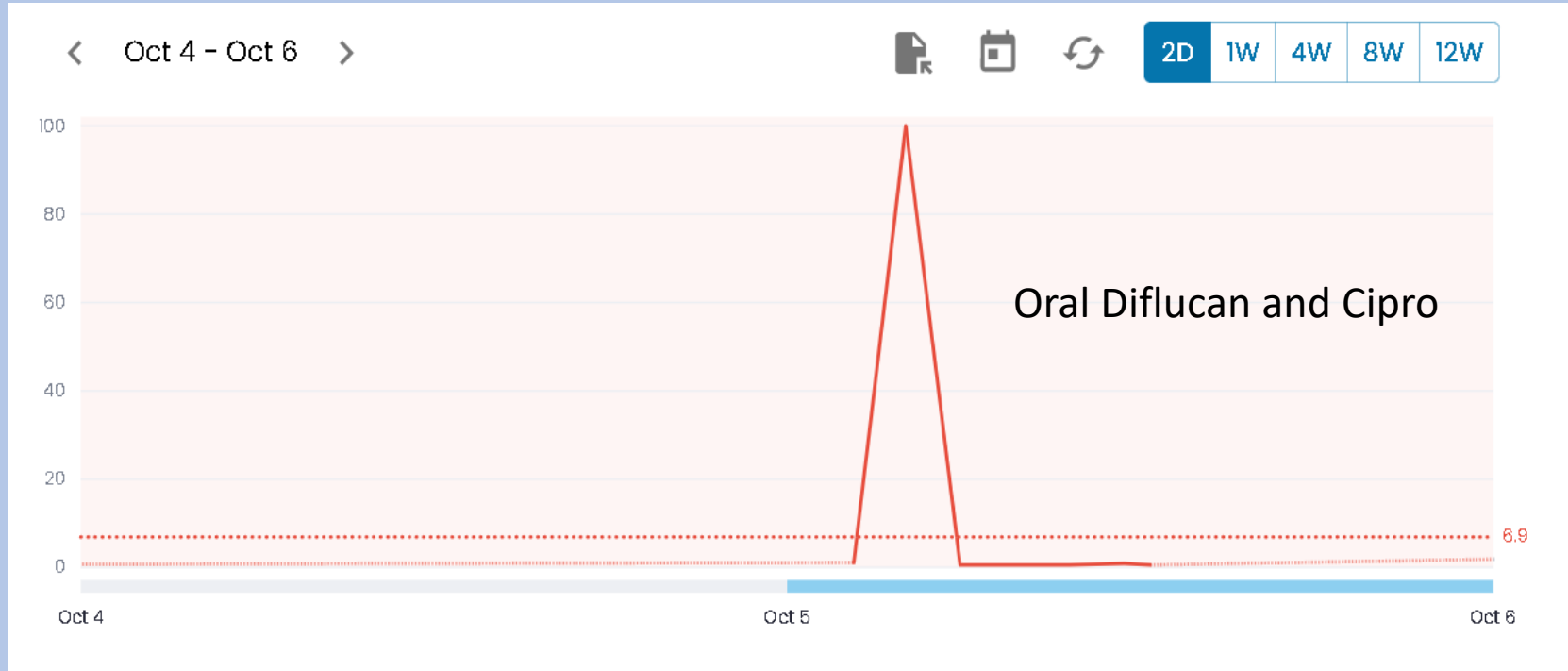
Gram Stain	Negative
Body Fluid Culture	Alcaligenes Faecalis
	Pseudomonas aeruginosa
	Fungus
Anaerobic Culture	No Growth
Exit Sit Culture	Pseudomonas aeruginosa
	Alcaligenes Faecalis

Subsequent Cell Counts

	10/5/22	10/26/22
Appearance	Colorless	Colorless
Color	Clear	Clear
WBC's	44	24
RBC's	375	<1000
Neutrophil	86	44
Mononuclear Cells	8	3
Lymphocytes	6	53

*Treated with Vancomycin and Gentamycin

*Additional Cultures drawn 10/26/22 were clear



TURBIDITY MONITORING- EVENT 3

CONCLUSIONS

- Effluent analysis allows for early detection of peritonitis
- Subsequent Studies are in process showing the ability to treat patients prior to symptoms
- False Positives in Peritonitis Detection are often clinically actionable

QUESTIONS?

References

- 1 Szeto, C.C. The new ISPD peritonitis guideline. Ren Replace Ther 4, 7 (2018).
- 2 Li PK-T, Chow KM, Cho Y, et al. ISPD peritonitis guideline recommendations: 2022 update on prevention and treatment. Peritoneal Dialysis International. 2022;42(2):110-153. doi:10.1177/08968608221080586
- 3 Perl, Jeffrey et al. "Peritoneal Dialysis-Related Infection Rates and Outcomes: Results From the Peritoneal Dialysis Outcomes and Practice Patterns Study (PDOPPS)." American journal of kidney diseases : the official journal of the National Kidney Foundation vol. 76,1 (2020): 42-53. doi:10.1053/j.ajkd.2019.09.016