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Establishing a Core Outcome Measure for Peritoneal Dialysis-related Peritonitis: A Standardized Outcomes in Nephrology—Peritoneal Dialysis Consensus Workshop Report



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# Establishing a Core Outcome Measure for Peritoneal Dialysis-related Peritonitis: A Standardized Outcomes in Nephrology—Peritoneal Dialysis Consensus Workshop Report

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**Introduction:** Peritoneal dialysis (PD)-related peritonitis is one of the leading causes of discontinuation of PD and is considered a critically important outcome for patients on PD. However, there is no universally accepted method of measuring this outcome in clinical trials.

**Methods:** We convened an online consensus workshop to establish a core outcome measure for PD-related peritonitis in clinical trials.

**Results:** A total of 53 participants, including 18 patients and caregivers, from 12 countries engaged in breakout discussions in this workshop. Transcripts were analyzed thematically. We identified the following 3 themes: (i) feasibility and applicability across diverse settings, which reflected the difficulty with implementing laboratory-based measures in resource-limited environments; (ii) ensuring validity, which included minimizing false positives and considering the specificity of symptoms; and (iii) being meaningful and tangible to patients, which meant that the measure should be easy to interpret, reflect the impact that symptoms have on patients, and promote transparency by standardizing the reporting of peritonitis among dialysis units.

**Conclusion:** A core outcome measure for PD-related peritonitis should include both symptom-based and laboratory-based criteria. Thus, the International Society for Peritoneal Dialysis (ISPD) definition of peritonitis is acceptable. However, there should be consideration of reporting suspected peritonitis in cases where laboratory confirmation is not possible. The measure should include all infections from the time of catheter insertion and capture both the rate of infection and the number of patients who remain peritonitis free.

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A core outcome measure with these features would increase the impact of clinical trials on the care and decision-making of patients receiving PD.

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KEYWORDS: core outcome measure; peritoneal dialysis; peritonitis; trial design


## BACKGROUND

PD-related peritonitis is the most common type of PD-related infection and is a leading cause of discontinuation of PD.[1–3] As the most serious type of PD-related infection, it can result in hospitalizations, permanent transfer to hemodialysis, and even death, disrupting patients' lives with adverse emotional and physical effects.[4–6]

Despite this, peritonitis is not routinely or consistently reported in studies of patients on PD. The ISPD published guidelines in 2022 which recommended that a diagnosis of peritonitis be made if at least 2 of the 3 following criteria are present: (i) clinical features consistent with peritonitis, that is, abdominal pain and/or cloudy dialysis effluent; (ii) dialysis effluent white blood cell count $> 100/\mu l$ or $>0.1 \times 10^9/l$ (after a dwell time of at least 2 hours), with >50% polymorphonuclear cells; and (iii) positive dialysis effluent culture.[7] Yet, a systematic review of 77 studies that reported PD-related peritonitis found that in almost a third of the studies, the outcome was not even defined.[8] The remaining studies used varying criteria to define peritonitis. Such inconsistencies make it difficult to compare the results across trials. Standardizing the measurement of PD-related peritonitis would make clinical trials more meaningful and relevant to patients, caregivers, clinicians, and other stakeholders.

PD-related infection was established as one of the critically important core outcomes to be measured in every clinical trial in PD, based on the shared priorities of >900 patients, caregivers, and health professionals from 68 countries who participated in the Standardized Outcomes in Nephrology (SONG)-PD initiative.[9–11] We convened a stakeholder workshop to identify the essential features of a core outcome measure for PD-related peritonitis, the most serious infection. This workshop report summarizes the perspectives of the patients, caregivers, and health care professionals on defining a core outcome measure for PD-related peritonitis to be used in all trials of patients on PD.

## SONG-PD PD-Related Peritonitis Workshop

### *Context and Scope*

The SONG-PD PD-Related Infection Consensus Workshop was held on September 23, 2020, to establish a core outcome measure for PD-related infection. We narrowed PD-related infections to PD-related peritonitis because the feedback from the SONG-PD process was that peritonitis was the key infection patients, caregivers, and clinicians were most concerned with preventing.[9–11] The workshop was held using a Zoom video conferencing to enable broad and diverse participation.

### *Attendees and Contributors*

The 53 workshop attendees included 18 patients and caregivers and 35 health professionals from 12 different countries (Australia, Austria, Canada, Colombia, France, Ghana, Hong Kong, Japan, Saudi Arabia, Singapore, United Kingdom, and the United States). Health professionals included nephrologists, nurses, researchers, industry representatives, and policy makers. We reached out to health professionals around the world with a variety of roles, including clinicians and researchers with a strong interest in PD, leaders in or advisors to relevant professional societies (including the ISPD), regulatory agencies (including the Centers for Disease Control in the United States), registries (Australia and New Zealand Dialysis and Transplant Registry, UK Renal Registry), and dialysis organizations. Patients and caregivers were invited by SONG-PD Infection Workshop Investigators. If invitees were unable to attend the workshop, they were asked to provide feedback before the workshop and review and add to this report as contributors. The full list of SONG-PD Infection Consensus Workshop attendees and contributors is provided in the Appendix.

### Workshop Program and Materials

The workshop program is available as Supplementary File S1. Attendees and contributors received this program and background materials before the workshop. The workshop began with a brief overview of the SONG-PD process and results, the systematic review of studies on PD peritonitis, and the questions for the breakout discussions. Participants then joined 1 of 6 breakout groups, each consisted of 8 to 9 people, including 3 patients or caregivers, a facilitator, and a co-facilitator.

All facilitators used the same question guide to moderate the discussion. Participants were asked whether the 2016 ISPD-recommended definition should be used for PD-related peritonitis, if the need for culture or cell count limited the feasibility of the definition, and whether the definition was relevant to patients. They also discussed whether the measure should report the

rate of peritonitis episodes alone or also include the percentage of patients affected, and at what time point the measure should start being measured.

Participants returned from the breakout discussion to join a plenary session where a representative from each group presented a summary of their discussion. The workshop chair (JP) concluded by summarizing the recommendations and key points of discussion that were made.

All the plenary and breakout sessions were audio-recorded and transcribed verbatim. The transcripts were entered into HyperRESEARCH software (version 3.7.2 m ResearchWare Inc., Randolph, MA). JIS used thematic analysis to review the transcripts line by line and inductively identify themes. The research team discussed and revised the themes to ensure that they reflected the full range and depth of the participants' discussion on the topic. A draft workshop report was sent to attendees and contributors for feedback, and these additional comments were incorporated into the final report.

## Summary of Workshop Discussion

We identified the following 3 themes that expressed the stakeholder's perspectives on a core outcome measure for PD-related peritonitis: (i) feasibility and applicability across diverse settings; (ii) ensuring validity; and (iii) being meaningful and tangible to patients. We describe subsequently these themes and their subthemes with supporting quotations in Table 1.

### *Feasibility and Applicability Across Diverse Settings*

*Difficulty With Implementing Laboratory-Based Measures in Resource-Limited Environments.* Although participants generally supported the ISPD's recommended definition for peritonitis, there was concern that the necessity of a laboratory-based measure to make the diagnosis would make it difficult to capture PD-related peritonitis in settings where a cell count or culture was not readily accessible. Such environments include not only lower income countries but also patients in rural areas who could not easily provide a sample for testing. This limitation is particularly salient given that PD is a home modality, as opposed to in-center dialysis where laboratory resources are generally more accessible. As 1 patient expressed, "we need to make sure that we can include those people in countries that don't have access or ready access to cell counts and cultures and such, because we'll be losing a large number of people that would be contributing to this." One suggestion was to "apply the ISPD criteria where a cell count and culture are available, but in areas where they aren't, one could consider some measure called probable or suspected peritonitis based on symptoms and response to treatment alone."

*Capturing Data Relevant to Clinical, Research, and Regulatory Settings.* Although the core outcome measure for PD-related peritonitis is primarily intended for clinical trials, participants felt that it should be translatable to all types of research, clinical, and regulatory settings, because the goal is to be able to "implement research into practice." For instance, regarding the time point at which peritonitis episodes should be recorded, several participants noted that it might depend on the research question: trials focused on training might only need to capture peritonitis after training had started and trials enrolling prevalent patients were not likely to have data on episodes before enrolment. However, for both clinical and regulatory settings, attendees expressed the importance of capturing episodes from the time of PD catheter insertion to capture pretraining peritonitis. In both settings, the timing of the infection is key because it reflects what factors might be responsible; for instance, peritonitis before training would suggest that changes to perioperative practices are needed. Similarly, participants supported an outcome measure that reflects whether there were multiple infections per patient. Not only is this information needed to conduct meta-analyses, but it is also important in clinical and regulatory settings in determining whether there is a systemic (center-level) versus an individual or case-mix (patient level) issue that needs to be addressed. "If you start seeing either a lot of cases from one patient or a lot of cases per clinic and this stands out, then obviously there's an issue that needs to be investigated."

*Decreasing Burden of Reporting.* Attendees emphasized balancing the collection of crucial information with decreasing the burden of reporting on trials. "If you load them up too much with a whole pile of measures, that actually adds trial complexity and expense." This dampened enthusiasm for recording peritonitis-associated hospitalizations, because "then you have to talk about how many days of hospitalization, all sorts of stuff. So, it gets quite complicated." Similarly, choosing to start data collection at the time of catheter insertion was considered simpler than starting from the end of training because "it's much easier to collect a procedure date than first day at home." It would be however "quite difficult" for all trials to use this start point, because "not all trials will be of patients who are just starting PD." Furthermore, a US participant warned that it was challenging to capture peritonitis that occurs after catheter insertion and before training starts, because in the US, dialysis units are the ones that track peritonitis, and units typically do not follow patients until they start training.

**Table 1.** Selected illustrative quotations for each theme

| | |
|---|---|
| **Feasibility and applicability across diverse settings** | |
| Difficulty with implementing laboratory-based measures in resource-limited environments | "Also, people that might be like 3 hours away and solos. So, are they going to drive? Having driven and lived with peritonitis, are you going to drive 3 hours to drop a bag off [to get laboratory-based measures]?" (Patient, group 1)<br>"From resource constrained regions, we really have problems having positive cultures." (Health professional, group 2)<br>"Certainly, for remote areas, even in Australia, I think we do encounter that issue of not being able to have a cell count within a reasonable time." (Health professional, group 3) |
| Capturing data relevant to clinical, research, and regulatory settings | "What we're aiming for is embedded research. So, a trial pretty much mirrors real world clinical practice. At the end of the day, whatever the trial result is, you have to actually implement it into practice. And that's much easier if it's just a very easy condition because it's actually true world practice." (Health professional, group 2)<br>"Thinking more from a surveillance, health care associated infection, how can we prevent infection? So, I think it's important to know kind of when they're occurring, throughout the spectrum, and to kind of be able to identify things that we could improve to prevent them." (Health professional, group 4) |
| Decreasing burden of reporting | "If you load them up too much with a whole pile of measures that actually adds trial complexity and expense." (Health professional, group 2)<br>"We should also be careful. I mean, this is a core outcome that we're asking people to report. I think you can only ask them to report so many things otherwise it becomes a big burden for a trial." (Health professional, group 5) |
| **Ensuring validity** | |
| Minimizing false positives | "Do we want to be really sure that this is a peritonitis episode and make sure that we don't include episodes that aren't peritonitis, or do we want to cast a wide net and make sure we capture all of them, but also understand that we're going to get some episodes that aren't?" (Health professional, group 1)<br>"I feel if the purpose here is for really a trial setting or studies that then we would want an outcome definition that would be quite rigorous so that you could depend on the results from the study." (Health professional, group 2)<br>"If every one of those episodes gets counted as an episode of peritonitis, we're going to have countries throw their hands up, so to speak and say, 'We're not doing PD anymore, because our peritonitis rate is godawful.' And I don't think we want that. I don't think we can have that." (Health professional, group 6) |
| Specificity of signs and symptoms | "When I first started dialysis, it was hard to really tell what sensations I was feeling. But over time, as long as I felt the sensation and then did not see cloudy fluids within the following day or 2, I was usually pretty assured as to the lack of infection. And so, I feel that the clearest indicator, at least from a patient perspective is whether or not the solution coming out is cloudy." (Patient, group 4)<br>"As with the pain, yeah. It could even just be gas sometimes; you just don't know." (Patient, group 4) |
| Distinguishing severity | "Knowing that getting the peritonitis episode and it actually means that you can no longer do PD. That's a big thing for patients to know." (Patient, group 5)<br>"I think 1 of the points about hospitalization though, is that in different parts of the world, the practice is quite different. So, for example, I think in Australia, New Zealand, the hospitalization rates are higher than in Canada, for example. And I don't think that's related necessarily to peritonitis severity, but more related just to what is standard practice in that part of the world." (Health professional, group 5) |
| **Being meaningful and tangible to patients** | |
| Reflecting the experiential relevance of symptoms and catheter insertion | "Patients aren't going to have access to a lot of, for example, the testing, it's pretty inconsequential to the patient, whether or not the cell counts match up to what the clinical definition is. Whereas, what I, as a patient, do see, or experience rather, is discomfort, pain and visually verified that the effluence is cloudy or not." (Patient, group 4)<br>"I also agree about counting peritonitis from the minute the catheter is inserted into my abdomen, because that's when I'm vulnerable. And in my mind, that's when I started PD." (Patient, group 6) |
| Ease of interpretation of the measure | "I would rather see it in counts as far as whole people counts, like percentages or something. It's hard for me to understand if it would be a, the way it's currently done sometimes, where it looks like it's just a small [fraction] per person, I think is hard to comprehend." (Patient, group 3)<br>"When you know that there is clustering of infections, I think that's an important thing to present to patients so that they're able to make a more informed decision without fully understanding the implications of the stats behind it." (Patient, group 4) |
| Promoting transparency and education | "I think right now, there's a real lack of transparency to us when we're looking at making our choices, especially in regards to peritonitis. Patients don't know. I've been asked before, 'Does everyone get peritonitis?' by other patients, and I don't know if I have a real straight answer for anyone other than, 'I hope not.'" (Patient, group 3)<br>"I think when you're making a decision about what type of dialysis you're about to start, definitely hearing the horror stories about the peritonitis is a big factor. So if you were able to clarify that it's a smaller amount of patients that are actually getting the larger amounts of peritonitis, then it sort of shows people that really learning the proper skills and making sure that their technique while they're doing peritonitis is the main factor in stopping that actually happening, rather than it just being a common thing that happens to people on PD." (Patient, group 5) |

PD, peritoneal dialysis.

## *Ensuring Validity*

*Minimizing False Positives.* Although many participants considered defining peritonitis based on just clinical features given that laboratory confirmation is not universally available, they weighed this against "increasing the likelihood of labeling something as

peritonitis that isn't." As 1 participant voiced, "the purpose here is for really a trial setting, so we would want an outcome definition that would be quite rigorous so that you could depend on the results from the study." This could have particular ramifications in the very settings where laboratory results are scarce: "If every one of these [symptom-only defined] episodes gets counted as an episode of peritonitis, we're going to have countries throw up their hands up, so to speak, and say, 'We're not doing PD anymore, because our peritonitis rate is godawful.'"

*Specificity of Signs and Symptoms.* Patients noted that some signs and symptoms are more specific than others. In particular, they found cloudy fluid to be fairly specific but that pain was nonspecific. One patient explained that especially when he first started PD, it was difficult to distinguish between "discomfort" or drain pain and unusual pain that might suggest peritonitis. "The key indicator to me is still the cloudiness in the effluent." Because of this, many agreed that abdominal pain alone should not be sufficient to define peritonitis.

*Distinguishing Severity.* Attendees acknowledged that reporting the severity of an episode of peritonitis was useful because peritonitis that is severe enough to require hospitalization and discontinuation of PD has significant consequences for the patient, provider, and the health care system. As 1 patient framed it, "I'd be interested in knowing how often peritonitis leads to having to go to hemodialysis, because that's the big decision-making part." Others noted that because the indications for hospitalization are not standardized, hospitalization rates might not reflect the severity of the episode but rather the practice patterns of the provider. Some participants felt that because discontinuation of PD was another SONG-PD core outcome, there might be a way to integrate both measures to extrapolate which peritonitis episodes resulted in PD cessation.

### Being Meaningful and Tangible to Patients

*Reflecting the Experiential Relevance of Symptoms and Catheter Insertion.* When considering the definition of peritonitis, patients and caregivers noted that symptoms were of paramount importance to them as these are the warning signs that they must monitor for and that trigger empirical treatment. They noted, "we only go by symptoms from the carer or the patient level" because "we can't do all this sampling and testing, but we do know what we see." Similarly, patients agreed that episodes should be captured starting at the time of catheter insertion, "because that's when [they are] vulnerable. And in [their] mind, that's when [they] started PD."

*Ease of Interpretation of the Measure.* Participants agreed that the measure should be easy for patients and caregivers to understand. The ISPD recommends reporting peritonitis rates as episodes per patient-year at risk.[7] However, this rate is usually a fraction of an episode per patient-year. Some patients and caregivers explained that they "would rather see it in counts as far as whole people counts, like percentages. The way it's currently done sometimes, where it looks like it's just a small [fraction] per person, is hard to comprehend." They also felt that the measure should clearly express whether there were multiple infections per patient. For example, a measure that reports the percentage of patients who remained peritonitis free would "provide better context because you know there is clustering. It's an important thing to present to patients so that they're able to make a more informed decision without fully understanding the implications of the statistics behind it."

*Promoting Transparency and Education.* Patients and caregivers were hopeful that standardizing the reporting of peritonitis would promote units to be more transparent about the infection rates in their programs. Patients agreed that peritonitis rates were "certainly not something that [they] heard or talked a lot about," even though it was something they would want to know when choosing between dialysis units. Participants also considered having a measure that reflects the percentage of patients who are peritonitis free in addition to the overall rate to be essential information, because it would help patients understand that the risk of infection differs by patient. "We see that peritonitis episodes tend to cluster in about 30% or 40% of our patients. So, I think that's relevant for caregivers and patients to know that a large subset of patients are never going to get a peritonitis episode." This would be particularly relevant information to share with patients who are choosing a dialysis modality, because many may have only heard "horror stories about peritonitis."

## DISCUSSION

Participants in a consensus workshop for establishing a core outcome measure for PD-associated peritonitis agreed that the definition should incorporate both clinical features and laboratory-based measures to ensure the validity of the definition because signs and symptoms, although most meaningful to patients, are not always specific. To acknowledge the difficulty with implementing laboratory-based measures in resource-limited environments, many advocated considering an additional diagnosis of "suspected peritonitis" that incorporated only clinical signs and symptoms in cases where laboratory results were not available. This would allow under-resourced areas to capture events, while being mindful of

the limitation imposed by the inability to confirm using laboratory technique. However, there ultimately was no consensus that this category should be a mandatory component of the outcome measure. There was consensus that peritonitis episodes should be tracked from the time of catheter insertion, when patients start being at risk. Because the outcome measure would ideally be translatable to clinical and regulatory settings where the goal is to prevent all peritonitis, starting at a later date would be suboptimal as it would risk missing pretraining episodes. Participants also agreed that the measure should report not only the overall peritonitis rate but also the percentage of patients who remained peritonitis free. Understanding whether there is clustering of infections among patients is relevant not only for determining the etiology of the infections but also for accurately communicating the risk of infection to patients. The measure should be easily interpretable by patients and caregivers, ideally expressing risk in whole numbers rather than fractions. Although participants acknowledged that reporting the severity of an infection would be ideal, most felt that it would unduly increase the burden of reporting. Finally, patients and caregivers hoped that a standardized outcome measure for PD-related peritonitis would encourage dialysis units to be transparent in reporting their infection rates.

The ISPD updated their guidelines on peritonitis in 2022, and the workshop findings were made available to the ISPD at the time the guidelines were draft. The 2022 guidelines kept the recommended definition for PD-related peritonitis published in 2016 that had been generally considered acceptable by workshop participants.[7] Consistent with the findings from this workshop, they recommend tracking the overall peritonitis rate and the percentage of patients per year who are peritonitis free. They suggest reporting peritonitis rates as number of episodes per patient-year. The ease of using this metric to compare rates will need to be weighed against the difficulty patients and caregivers have in interpreting risk as a fraction of an episode per patient-year. Finally, they agree with capturing peritonitis from the time of PD insertion, though they differentiate between pre-PD peritonitis which happens before the commencement of PD treatment ("i.e., first day of PD training or PD treatment in a hospital or home with the intention of continuing PD long-term, whichever occurs first") and PD-related peritonitis, which they define as episodes that occur after PD commencement.

The workshop included patients, caregivers, clinicians, researchers, and representatives from industry and regulatory agencies globally. However, we acknowledge that a limitation of the workshop is that all the participants were English speaking and had access to videoconferencing.

**Table 2.** Summary of workshop recommendations for establishing a core outcome measure for peritoneal dialysis-related peritonitis

| Implications for establishing a core outcome measure for PD-related peritonitis |
|---|
| • The ISPD definition for peritonitis is generally acceptable because it incorporates both clinical features and laboratory-based measures, ensuring validity |
| • The measure should capture both the overall rate of peritonitis and the percentage of patients who remain peritonitis free |
| • All peritonitis episodes should be captured starting from the time of catheter insertion. (Updated in the 2022 ISPD guidelines) |
| • The measure should be easily interpretable by patients and caregivers, ideally expressing risk in whole numbers rather than fractions |
| • Reporting suspected (vs. confirmed) peritonitis in cases where there are signs or symptoms of peritonitis, but laboratory confirmation is not possible, should be considered in studies conducted in resource-limited environments. (Not included in 2022 ISPD guidelines) |

ISPD, International Society for Peritoneal Dialysis; PD, peritoneal dialysis.

Recommendations from this workshop (illustrated in Table 2) informed the establishment of a core outcome measure for PD-associated peritonitis. Although the measure is meant to standardize the reporting of clinical trials in patients on PD, participants also advocated for its use in clinical practice and research not involving trials. Collaborations with international organizations such as grant-funding agencies, clinical trial registries, and editorial boards of medical journals are ongoing to encourage its implementation. This will include working with US policymakers to adopt peritonitis as an outcome that must be reported, including episodes that occur before PD commencement. Such work is already underway as part of the Optimizing Prevention of PD-Associated Peritonitis in the US study, which aims to standardize reporting of peritonitis episodes in US dialysis clinics.[12] The adoption of a standard, meaningful outcome measure that is consistently reported will increase the impact of trial results by simplifying the comparison and evaluation of different interventions, which will ultimately inform shared decision-making that improves the care of patients on PD.

## APPENDIX

### SONG-PD Infection Workshop Investigators

*SONG Executive Committee.* Jonathan Craig, Allison Tong, Angela Wang, Brenda Hemmelgarn, Braden Manns, David Wheeler, John Gill, Peter Tugwell, Roberto Pecoits-Filho, Sally Crowe, Tess Harris, Wim Van Biesen, and Wolfgang Winkelmayer.

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## DISCLOSURE

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## SUPPLEMENTARY MATERIAL

Supplementary File (PDF)

**File S1.** SONG-PD PD-related infection consensus workshop program.

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