KEY QUESTION 1

In adult patients needing renal replacement therapy who are diagnosed with a hernia, should hernia repair be staged or done simultaneously with peritoneal dialysis catheter placement?	
POPULATION:	adult patients undergoing peritoneal dialysis with concomitant hernia
INTERVENTION:	Staged repair
COMPARISON:	Simultaneous repair
MAIN OUTCOMES:	Bleeding; Hernia Recurrence - Early (<1mon); Hernia Recurrence - Late (>1mon); Exit Site Infection; Leakage; Mortality;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● **Yes** ○ Varies ○ Don't know		Yes

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● **Moderate** ○ Large ○ Varies	There were two comparative, observational studies looking at staged vs. simultaneous hernia repair with PD catheter placement.	Differences in outcome of peritonitis swayed to moderate. Moderate 100%

○ Don't know	For all outcomes of interest there were zero events in both cohorts across these two studies, thus they are non-informative to decision making. **<u>Single Arm Data (I2 presented if >40%):</u>** **Bleeding:** Staged (2 studies) 1.6% (0.3%-7.5%) Simultaneous (1 study) 2.8% (0.2%-32.2%) **Leakage:** Staged (2 studies) 3.8% (0.5%-22.7%) Simultaneous (5 studies) 10.4% (4.8%-20.9%) **Peritonitis:** Staged (1 study) 6.4% (2.4%-15.7%) Simultaneous (2 studies) 35.7% (8.7%-76.5%; I2 62%)	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ● **Small** ○ Trivial ○ Varies ○ Don't know	**<u>Single Arm Data (I2 presented if >40%):</u>** **Early Catheter Dysfunction:** Staged (1 study) 4.8% (0.7%-27.1%) Simultaneous (1 study) 2.3% (0.1%-27.7%) **Early Hernia Recurrence (<1mon):** Staged (4 studies) 4% (1%-14.6%) Simultaneous (5 studies) 3% (0.9%-9.9%) **Late Hernia Recurrence (<u>≥</u>1mon):** Staged (4 studies) 9.8% (5.1%-18%) Simultaneous (5 studies) 7.1% (2.1%-21.6%) **Exit Site Infection:** Staged (1 study) 10% (0.6%-67.4%) Simultaneous (2 studies) 4.1% (0.8%-18.1%) **Mortality:** Staged (4 studies) 5.3% (2.3%-11.7%) Simultaneous (7 studies) 2.2% (1.1%-4.5%)	Small on basis of exit site infection Mortality events cause of death not related to surgical intervention but underlying disease Small 100%

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

● **Very low** ○ Low ○ Moderate ○ High ○ No included studies	<table><tr><th>Outcomes</th><th>Importance</th><th>Certainty of the evidence (GRADE)</th></tr><tr><td>Bleeding</td><td>IMPORTANT</td><td>⨁◯◯◯ Very low[a]</td></tr><tr><td>Hernia Recurrence - Early (<1mon)</td><td>CRITICAL</td><td>⨁◯◯◯ Very low[a]</td></tr><tr><td>Hernia Recurrence - Late (>1mon)</td><td>IMPORTANT</td><td>⨁◯◯◯ Very low[a]</td></tr><tr><td>Exit Site Infection</td><td>IMPORTANT</td><td>⨁◯◯◯ Very low[a]</td></tr><tr><td>Leakage</td><td>IMPORTANT</td><td>⨁◯◯◯ Very low[a]</td></tr><tr><td>Mortality</td><td>CRITICAL</td><td>⨁◯◯◯ Very low[a]</td></tr></table> a. No statistical matching was done within this study(ies).	Very low 100%

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● **Possibly important uncertainty or variability** ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		possible important uncertainty 100%

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● **Probably favors the intervention** ○ Favors the intervention ○ Varies ○ Don't know		probably favors the intervention (staged) 100%

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● **Probably yes** ○ Yes ○ Varies ○ Don't know		Patient may not want to undergo anesthesia twice. Could also delay PD initiation and require HD in the interim Probably yes 100%

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● **Yes** ○ Varies ○ Don't know		Yes 100%

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know

	JUDGEMENT						
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	•	○

Conditional recommendation for the intervention.

CONCLUSIONS

Recommendation

Justification

Subgroup considerations

If patient needs to initiate PD more quickly, can do it simultaneously.
In hernia subset and early start subset, look at whether low volume group had better outcomes.
Mesh use and position
Breakdown of hernia type umbilical vs ventral vs inguinal

Implementation considerations

Monitoring and evaluation

Research priorities

Creating a protocol for PD protocols (volume regimen, time to initiation, frequency) after hernia repair.
Use of mesh and positioning of mesh (Laparoscopic approach)

KEY QUESTION 2A

Should urgent start or traditional start be used for adult patients who are initiating peritoneal dialysis?	
POPULATION:	Adult patient who are initiating peritoneal dialysis
INTERVENTION:	Urgent start
COMPARISON:	Traditional start
MAIN OUTCOMES:	Bleeding; Catheter dysfunction - Early (<3mon); Catheter dysfunction - Late (>=3mon); Exit Site Infection; Leakage; Mortality; Peritonitis;
SETTING:	
PERSPECTIVE:	patient centered
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know		Yes 100%

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies		Small 100%

○ Don't know		

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Traditional Start	Risk difference with Urgent Start
Catheter dysfunction - Late (>=3mon)	828 (4 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 0.69** (0.43 to 1.12)	Study population	
				236 per 1,000	**60 fewer per 1,000** (119 fewer to 21 more)
Exit Site Infection	914 (6 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 0.84** (0.42 to 1.71)	Study population	
				74 per 1,000	**11 fewer per 1,000** (41 fewer to 46 more)

a. There was a small event size in addition to estimated effects that ranged from significant benefit to significant harms.
b. No formal statistical matching and there were other confounding factors not accounted for, thus cannot be certain that the two groups are equal.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ● Moderate ○ Small ○ Trivial ○ Varies ○ Don't know		Moderate 100%

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Traditional Start	Risk difference with Urgent Start
Bleeding	129 (1 observational study)	⨁◯◯◯ Very low[a,b]	**OR 8.72** (0.88 to 86.84)	Study population	
				11 per 1,000	**75 more per 1,000** (1 fewer to 472 more)

Catheter dysfunction - Early (<3mon)	468 (6 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 2.87** (0.95 to 8.69)	Study population	
				43 per 1,000	**71 more per 1,000** (2 fewer to 238 more)
Leakage	1018 (8 observational studies)	⨁◯◯◯ Very low[a,d]	**OR 3.42** (1.69 to 6.89)	Study population	
				37 per 1,000	**78 more per 1,000** (24 more to 171 more)
Mortality	636 (4 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 2.36** (1.29 to 4.32)	Study population	
				123 per 1,000	**125 more per 1,000** (30 more to 254 more)
Peritonitis	1167 (9 observational studies)	⨁◯◯◯ Very low[a,e]	**OR 1.41** (0.95 to 2.09)	Study population	
				151 per 1,000	**49 more per 1,000** (6 fewer to 120 more)

a. No formal statistical matching and there were other confounding factors not accounted for, thus cannot be certain that the two groups are equal.
b. There was a very small sample size and even smaller event size, which increases the fragility of the outcome. Furthermore, the range of effects crosses several clinically important thresholds.
c. There is some inconsistency with a few included studies demonstrating the opposite effect of the pooled effect (I2 49%).
d. There was a small event size in addition to estimated effects that ranged from significant benefit to significant harms.
e. There was a small event size in addition to estimated effects that ranged across several clinically relevant thresholds.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

● Very low ○ Low ○ Moderate ○ High ○ No included studies		Very low 100%

Outcomes	Importance	Certainty of the evidence (GRADE)
Bleeding		⨁◯◯◯ Very low[a,b]
Catheter dysfunction - Early (<3mon)		⨁◯◯◯ Very low[a,b,c]
Catheter dysfunction - Late (>=3mon)		⨁◯◯◯ Very low[a,d]
Exit Site Infection		⨁◯◯◯ Very low[a,d]
Leakage		⨁◯◯◯ Very low[a,d]
Mortality		⨁◯◯◯ Very low[a,b]
Peritonitis		⨁◯◯◯ Very low[a,e]

a. No formal statistical matching and there were other confounding factors not accounted for, thus cannot be certain that the two groups are equal.
b. There was a very small sample size and even smaller event size, which increases the fragility of the outcome. Furthermore, the range of effects crosses several clinically important thresholds.
c. There is some inconsistency with a few included studies demonstrating the opposite effect of the pooled effect (I2 49%).
d. There was a small event size in addition to estimated effects that ranged from significant benefit to significant harms.
e. There was a small event size in addition to estimated effects that ranged across several clinically relevant thresholds.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability		Probably no important uncertainty or variability 100%

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ● Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know		Probably favors the comparison 100%

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know		Probably yes 100%

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ● Varies		Varies 100%

○ Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	**Moderate**	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	**Probably favors the comparison**	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		**Varies**	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	**Conditional recommendation against the intervention**	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	●	○	○	○

CONCLUSIONS

Recommendation

In adult patients who are initiating PD, the panel suggests traditional start of PD rather than urgent start of PD.

Justification

This recommendation is specifically in patients who have the option of waiting or starting on a more urgent basis. For adult patients who require urgent initiation of renal replacement therapy the panel acknowledges that the risks of urgent start PD may seem relatively small compared to the risks associated with interval HD followed by traditional start of PD.

Subgroup considerations

Urgency of renal replacement therapy
Breakdown by technique
Immunosuppressed patients
Repeat PD cath vs. first PD cath

Implementation considerations

individualize per patient per disease process

Monitoring and evaluation

Research priorities

Need to study PD vs. HD
Investigate source of lower cath dys with urgent start
Low volume in urgent start
Multi-center, RCT studies with same technique

KEY QUESTION 3

Should concomitant surgeries or PD placement only be done for adult and pediatric patients who are initiating peritoneal dialysis?	
POPULATION:	Adult patient who are initiating peritoneal dialysis
INTERVENTION:	Concomitant Surgeries
COMPARISON:	PD placement only
MAIN OUTCOMES:	
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o No o Probably no o Probably yes o Yes o Varies o Don't know		

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
o Trivial o Small o Moderate o Large o Varies	There were no comparative studies addressing this question. Below is single arm data for patients that underwent ***clean-contaminated/contaminated cases concomitantly*** with their PD catheter placement.	

○ Don't know	**Single Arm Data (I2 presented if >40%):** Bleeding (4 studies): 22.1% (3.4%-69.2%; I2 64.1%) Catheter Dysfunction (3 studies): 7.1% (1.8%-24.7%) Exit Site Infection (3 studies): 7.1% (1.8%-24.7%) Leakage (3 studies): 5.1% (1%-21.8%) Mortality (3 studies): 5.1% (1%-21.8%) Peritonitis (2 studies): 7.1% (1%-37.3%)	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ○ Small ○ Trivial ○ Varies ○ Don't know		

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Very low ○ Low ○ Moderate ○ High ○ No included studies		

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know		

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies ○ Don't know		

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ○ Yes ○ Varies		

○ Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	Yes		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	Very low	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	Probably yes	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	○	○	○

CONCLUSIONS

Recommendation

Justification

Subgroup considerations

Wound class – clean contaminated specifically
Biliary vs gastric vs sb vs lb

Implementation considerations

Monitoring and evaluation

Research priorities

Larger studies with outcomes clearly delineated.
Biliary vs gastric vs small bowel vs large bowel operations with concomitant pd cath placement.

KEY QUESTION 4

Should advanced laparoscopic insertion techniques or basic laparoscopic insertion techniques be used for adult and pediatric patients needing renal replacement therapy?	
POPULATION:	Adult patients needing renal replacement therapy
INTERVENTION:	Advanced laparoscopic insertion
COMPARISON:	Basic laparoscopic insertion
MAIN OUTCOMES:	Bleeding; Bowel Injury; Catheter Dysfunction - Early (<3mon); Catheter Dysfunction - Late (>3mon); Hernia Occurence; Exit Site Infection; Leakage; Mortality (no events, non-informative outcome); Peritonitis;
SETTING:	
PERSPECTIVE:	Patient centered
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote:** Yes (100%)	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large	**Vote:** Moderate (100%)	

○ Varies
○ Don't know

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Basic Lap	Risk difference with Adv Lap
Bleeding	935 (3 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 0.71** (0.13 to 3.95)	Study population	
				11 per 1,000	**3 fewer per 1,000** (9 fewer to 30 more)
Catheter Dysfunction - Late (>3mon)	695 (4 observational studies)	⨁◯◯◯ Very low[a]	**OR 0.23** (0.09 to 0.57)	Study population	
				253 per 1,000	**181 fewer per 1,000** (223 fewer to 91 fewer)
Hernia Occurence	1031 (2 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 0.65** (0.08 to 5.24)	Study population	
				41 per 1,000	**14 fewer per 1,000** (38 fewer to 142 more)
Exit Site Infection	1176 (5 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.41** (0.09 to 1.95)	Study population	
				42 per 1,000	**24 fewer per 1,000** (38 fewer to 37 more)
Peritonitis	714 (3 observational studies)	⨁◯◯◯ Very low[a,d]	**OR 0.91** (0.41 to 2.02)	Study population	
				175 per 1,000	**13 fewer per 1,000** (95 fewer to 125 more)

a. Included studies did not employ statistical matching which introduces some bias in the comparability of cohorts.
b. There was a very small event rate which introduces fragility into the outcome. Additionally, the range of effects spans several clinical thresholds.
c. There is some heterogeneity within this outcome as a single study demonstrated opposite findings of the others (more infections advanced lap rather than basic lap). No reasonable explanation could be determined from differences in population, selection, or risk of bias (I2 72%).
d. The range of effects crosses several clinically relevant thresholds, from important benefit to important harms.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

- ○ Large
- ○ Moderate
- ● Small
- ○ Trivial
- ○ Varies
- ○ Don't know

RESEARCH EVIDENCE

Vote: Small (100%)

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Basic Lap	Risk difference with Adv Lap
Bowel Injury	634 (1 observational study)	⨁◯◯◯ Very low[a,b]	**OR 2.64** (0.11 to 65.70)	Study population	
				0 per 1,000	**0 fewer per 1,000** (0 fewer to 0 fewer)
Catheter Dysfunction - Early (<3mon)	397 (1 observational study)	⨁◯◯◯ Very low[a,c]	**OR 6.33** (1.42 to 28.25)	Study population	
				11 per 1,000	**54 more per 1,000** (5 more to 227 more)
Leakage	1031 (2 observational studies)	⨁◯◯◯ Very low[a,c]	**OR 2.23** (0.37 to 13.29)	Study population	
				2 per 1,000	**3 more per 1,000** (2 fewer to 29 more)

a. There was a very small event rate which introduces fragility into the outcome. Additionally, the range of effects spans several clinical thresholds.
b. One of the interventions had a zero event rate and thus the absolute effects could not be calculated, however the confidence interval of the OR was very large.
c. Included studies did not employ statistical matching which introduces some bias in the comparability of cohorts.

ADDITIONAL CONSIDERATIONS

Study for early catheter dysfunction only had suture fixation as advanced lap

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	**Vote:** Very low (100%)	

Outcomes	Importance	Certainty of the evidence (GRADE)
Bleeding	CRITICAL	⨁◯◯◯ Very low[a,b]
Bowel Injury	IMPORTANT	⨁◯◯◯ Very low[b,c]
Catheter Dysfunction - Early (<3mon)	CRITICAL	⨁◯◯◯ Very low[a,b]
Catheter Dysfunction - Late (>3mon)	CRITICAL	⨁◯◯◯ Very low[a]
Hernia Occurence	IMPORTANT	⨁◯◯◯ Very low[a,b]
Exit Site Infection	IMPORTANT	⨁◯◯◯ Very low[a,b,d]
Leakage	IMPORTANT	⨁◯◯◯ Very low[a,b]
Mortality	CRITICAL	⨁◯◯◯ Very low[a,b]
Peritonitis	CRITICAL	⨁◯◯◯ Very low[a,e]

a. Included studies did not employ statistical matching which introduces some bias in the comparability of cohorts.
b. There was a very small event rate which introduces fragility into the outcome. Additionally, the range of effects spans several clinical thresholds.
c. One of the interventions had a zero event rate and thus the absolute effects could not be calculated, however the confidence interval of the OR was very large.
d. There is some heterogeneity within this outcome as a single study demonstrated opposite findings of the others (more infections advanced lap rather than basic lap). No reasonable explanation could be determined from differences in population, selection, or risk of bias (I2 72%).

	e. The range of effects crosses several clinically relevant thresholds, from important benefit to important harms.	

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	**Vote:** Probably no important uncertainty or variability (100%)	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	**Vote:** Probably favors the intervention (100%)	

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote:** Yes (100%)	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**Vote:** Probably yes (100%)	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	●	○

CONCLUSIONS

Recommendation

Vote: Conditional recommendation for the intervention (100%)

Justification

Subgroup considerations

- prior abd surgery/ presence of scar tissue
- obesity
- pts without omentum in the pelvis (? selective)

Implementation considerations

promote education of the advanced lap technique within SAGES membership

Monitoring and evaluation

Research priorities

- RCT, multicenter
- standardized lap advanced
- usage of suture fixation vs tunneling
- subgroup – previous abdominal surgeries
- Obesity
- Patients with small omentum – when to do omentopexy

KEY QUESTION 5 (Adult)

Should advanced laparoscopic insertion techniques or open insertion of PD catheters be used for adult patients needing renal replacement therapy?	
POPULATION:	Adult patients needing renal replacement therapy
INTERVENTION:	Advanced laparoscopic insertion
COMPARISON:	Open insertion
MAIN OUTCOMES:	Bleeding; Bowel Injury; Catheter Dysfunction - Early (<3mon); Catheter Dysfunction - Late (>3mon); Hernia Occurrence; Exit Site Infection; Dialysate leakage; Mortality; Peritonitis
SETTING:	
PERSPECTIVE:	**PATIENT CENTERED**
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote 6/24**: Yes 100%	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large	**Vote 6/24**: Moderate 100%	

○ Varies
○ Don't know

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Open	Risk difference with Adv Lap
Bowel Injury	850 (2 observational studies)	⨁◯◯◯ Very low[a,b]	**OR 0.46** (0.02 to 8.81)	Study population	
				3 per 1,000	**1 fewer per 1,000** (3 fewer to 21 more)
Catheter Dysfunction - Early (<3mon)	3699 (5 observational studies)	⨁◯◯◯ Very low[b,c]	**OR 0.25** (0.13 to 0.45)	Study population	
				57 per 1,000	**42 fewer per 1,000** (49 fewer to 31 fewer)
Catheter Dysfunction - Late (>3mon)	324 (3 observational studies)	⨁◯◯◯ Very low[c,d]	**OR 0.18** (0.06 to 0.50)	Study population	
				223 per 1,000	**174 fewer per 1,000** (206 fewer to 97 fewer)
Hernia Occurrence	1165 (8 observational studies)	⨁◯◯◯ Very low[b,c]	**OR 0.62** (0.30 to 1.30)	Study population	
				46 per 1,000	**17 fewer per 1,000** (32 fewer to 13 more)
Exit Site Infection	990 (7 observational studies)	⨁◯◯◯ Very low[b,c]	**OR 0.72** (0.41 to 1.25)	Study population	
				93 per 1,000	**24 fewer per 1,000** (53 fewer to 21 more)
Leakage	918 (6 observational studies)	⨁◯◯◯ Very low[c,e]	**OR 0.61** (0.24 to 1.55)	Study population	
				46 per 1,000	**17 fewer per 1,000** (34 fewer to 23 more)
Mortality	3801 (4 observational studies)	⨁◯◯◯ Very low[c,e]	**OR 0.63** (0.37 to 1.06)	Study population	
				42 per 1,000	**15 fewer per 1,000** (26 fewer to 2 more)

Peritonitis	1046 (8 observational studies)	⨁◯◯◯ Very low[c,e]	**OR 0.61** (0.39 to 0.96)	Study population	
				220 per 1,000	**73 fewer per 1,000** (121 fewer to 7 fewer)

a. The included studies had opposite findings for this outcome, although the event rate was quite low.
b. These studies had a small event rate. The range of effects spans several clinically relevant thresholds.
c. Included studies did not utilize statistical matching thus there may be some baseline imbalance in prognostic factors which may be associated with this outcome.
d. The small sample size and small event size introduces some fragility into this outcome.
e. Small event size and the range of effects crosses a clinically relevant threshold.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

○ Large
○ Moderate
○ Small
● Trivial
○ Varies
○ Don't know

RESEARCH EVIDENCE

Vote 6/24: Trivial 100%

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Open	Risk difference with Adv Lap
Bleeding	781 (4 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 1.15** (0.16 to 8.23)	Study population	
				15 per 1,000	**2 more per 1,000** (12 fewer to 96 more)

a. Included studies did not utilize statistical matching thus there may be some baseline imbalance in prognostic factors which may be associated with this outcome.
b. The included studies had opposite findings for this outcome, although the event rate was quite low.
c. These studies had a small event rate. The range of effects spans several clinically relevant thresholds.

ADDITIONAL CONSIDERATIONS

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	**Vote 6/24**: Very low 100%	

Outcomes	Importance	Certainty of the evidence (GRADE)
Bleeding	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Bowel Injury	IMPORTANT	⨁◯◯◯ Very low[b,c]
Catheter Dysfunction - Early (<3mon)	CRITICAL	⨁◯◯◯ Very low[a,c]
Catheter Dysfunction - Late (>3mon)	CRITICAL	⨁◯◯◯ Very low[a,d]
Hernia Occurrence	IMPORTANT	⨁◯◯◯ Very low[a,c]
Exit Site Infection	IMPORTANT	⨁◯◯◯ Very low[a,c]
Leakage	IMPORTANT	⨁◯◯◯ Very low[a,e]
Mortality	CRITICAL	⨁◯◯◯ Very low[a,e]

Peritonitis	CRITICAL	⨁◯◯◯ Very low[a,e]

a. Included studies did not utilize statistical matching thus there may be some baseline imbalance in prognostic factors which may be associated with this outcome.
b. The included studies had opposite findings for this outcome, although the event rate was quite low.
c. These studies had a small event rate. The range of effects spans several clinically relevant thresholds.
d. The small sample size and small event size introduces some fragility into this outcome.
e. Small event size and the range of effects crosses a clinically relevant threshold.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	**Vote 6/24**: Probably no important uncertainty of variability 100%	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	**Vote 6/24**: Probably favors intervention (Adv Lap) 100%	

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote 6/24**: Yes 100%	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**Vote 6/24**: Probably yes 100%	**Slater:** access to equipment/ training (however dont need much and laparoscopy is very wide spread at this point)

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know

	JUDGEMENT						
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	Conditional recommendation for either the intervention or the comparison	**Conditional recommendation for the intervention**	Strong recommendation for the intervention
○	○	○	•	○

CONCLUSIONS

Recommendation

Vote 6/24: Conditional for the intervention (Adv Lap) 100%

Justification

Subgroup considerations

Implementation considerations

Publish, present at meetings, record operation to disseminate advanced laparoscopic techniques.
Standard training for advanced lap technique.

Monitoring and evaluation

Research priorities

RCTs
Investigating omentopexy vs omentectomy
Patients populations: obesity, prior abdominal surgery (advanced lap includes lysis of adhesions so might translate into better function)

QUESTION 5 (Pediatric)

Should advanced laparoscopic insertion techniques or open insertion of PD catheters be used for pediatric patients needing renal replacement therapy?	
POPULATION:	Pediatric patients needing renal replacement therapy
INTERVENTION:	Advanced laparoscopic insertion
COMPARISON:	Open insertion
MAIN OUTCOMES:	Early Catheter Dysfunction (<=3mon); Late Catheter Dysfunction (>3mon); Hernia Occurrence ; Exit Site Infection; Leakage; Mortality; Requires operative salvage; Peritonitis;
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know		Yes 100%

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ○ Small ● Moderate ○ Large	Perioperative Mortality (≤ 30 days): Adv Lap 2.3% (0.1%-27.7%) vs. Open N/A	**Single Arm Data (I2 reported if >40%):** **Early Catheter Dysfunction:** Adv Lap 24.5% (14.4%-38.5%; I2 66.7%) vs. Open 32.8% (18.4%-51.2%; I2 94.2%)

○ Varies
○ Don't know

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Open	Risk difference with Adv Lap
Early Catheter Dysfunction (<=3mon)	562 (6 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.74** (0.46 to 1.19)	Study population	
				449 per 1,000	**73 fewer per 1,000** (176 fewer to 43 more)
Late Catheter Dysfunction (>3mon)	390 (4 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.22** (0.07 to 0.68)	Study population	
				613 per 1,000	**355 fewer per 1,000** (513 fewer to 94 fewer)
Leakage	370 (5 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.48** (0.17 to 1.40)	Study population	
				104 per 1,000	**51 fewer per 1,000** (85 fewer to 36 more)
Mortality	49 (1 observational study)	⨁◯◯◯ Very low[a,b,c]	**OR 0.26** (0.01 to 5.43)	Study population	
				91 per 1,000	**66 fewer per 1,000** (90 fewer to 261 more)
Requires operative salvage	144 (3 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.41** (0.04 to 4.40)	Study population	
				290 per 1,000	**146 fewer per 1,000** (274 fewer to 352 more)
Peritonitis	389 (5 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.37** (0.11 to 1.28)	Study population	
				282 per 1,000	**155 fewer per 1,000** (241 fewer to 53 more)

a. Included studies had a high risk of bias as determined by the Newcastle-Ottawa Scale due to lack of statistical matching and non-standardization of the procedures.
b. There was a small sample size and a smaller event size that could increase the fragility of the outcome.

Late Catheter Dysfunction: Adv Lap 30.8% (13.5%- 55.9%; I2 87.4%) vs. Open 60.3% (37.3%-79.4%; I2 88.9%)
***Leakage**: Adv Lap 10.9% (6.6%-17.4%) vs. Open 9.3% (5.8%-14.5%; I2 51.8%)
Requires Operative Salvage: Adv Lap 10.7% (5.7%- 19.4%) vs. Open 27.1% (9.1%-57.9%; I2 84.5%)
Peritonitis: Adv Lap 26% (8.9%-55.7%; I2 89.9%) vs. Open 26.8% (17.2%-39.2%; I2 85.5%)

***Does not match comparative studies in the direction of effects

moderate favoring advanced lap particularly late cath dysfunction

Moderate 100%

c. The range of effects crosses multiple clinically relevant thresholds.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT

○ Large
○ Moderate
○ Small
● Trivial
○ Varies
○ Don't know

RESEARCH EVIDENCE

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Open	Risk difference with Adv Lap
Hernia Occurrence	157 (1 observational study)	⨁◯◯◯ Very low[a,b,c]	**OR 1.84** (0.47 to 7.18)	Study population	
				88 per 1,000	**63 more per 1,000** (44 fewer to 320 more)
Exit Site Infection	442 (5 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 1.08** (0.46 to 2.55)	Study population	
				77 per 1,000	**6 more per 1,000** (40 fewer to 99 more)

a. Included studies had a high risk of bias as determined by the Newcastle-Ottawa Scale due to lack of statistical matching and non-standardization of the procedures.
b. There was a small sample size and a smaller event size that could increase the fragility of the outcome.
c. The range of effects crosses multiple clinically relevant thresholds.

ADDITIONAL CONSIDERATIONS

Single Arm Data (I2 reported if >40%):
Bleeding: Adv Lap 6.43% (1%-31%) vs. Open 0.69% (0.04%-10.1%)
***Hernia Occurrence**: Adv Lap 5.8% (1.8%-17%; I2 58.3%) vs. Open 11.6% (7.9%-16.8%)
Exit Site Infection: Adv Lap 9.4% (5.7%-15%) vs. Open 7.1% (4.9%-10.3%)

***Does not match comparative studies in the direction of effects

trivial 100%

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT

RESEARCH EVIDENCE

ADDITIONAL CONSIDERATIONS

● Very low
○ Low
○ Moderate
○ High
○ No included studies

Outcomes	Importance	Certainty of the evidence (GRADE)
Early Catheter Dysfunction (<=3mon)	CRITICAL	⨁◯◯◯ Very low[a,b,c]
Late Catheter Dysfunction (>3mon)	CRITICAL	⨁◯◯◯ Very low[a,b,c]
Hernia Occurrence	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Exit Site Infection	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Leakage	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Mortality	CRITICAL	⨁◯◯◯ Very low[a,b,c]
Requires operative salvage	CRITICAL	⨁◯◯◯ Very low[a,b,c]
Peritonitis	CRITICAL	⨁◯◯◯ Very low[a,b,c]

a. Included studies had a high risk of bias as determined by the Newcastle-Ottawa Scale due to lack of statistical matching and non-standardization of the procedures.
b. There was a small sample size and a smaller event size that could increase the fragility of the outcome.
c. The range of effects crosses multiple clinically relevant thresholds.

very low 100%

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● **Probably no important uncertainty or variability** ○ No important uncertainty or variability		probably no important uncertainty or variability 100%

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ○ Does not favor either the intervention or the comparison ● **Probably favors the intervention** ○ Favors the intervention ○ Varies ○ Don't know		probably favors the intervention 100%

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● **Probably yes** ○ Yes ○ Varies ○ Don't know		probably yes 100%

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● **Probably yes** ○ Yes ○ Varies		probably yes 100%

○ Don't know		

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	Small	**Moderate**	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	Small	**Trivial**		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	Does not favor either the intervention or the comparison	**Probably favors the intervention**	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention ○	Conditional recommendation against the intervention ○	Conditional recommendation for either the intervention or the comparison ○	**Conditional recommendation for the intervention** ●	Strong recommendation for the intervention ○

CONCLUSIONS

Recommendation

Justification

Subgroup considerations

Implementation considerations

Monitoring and evaluation

Research priorities

within the advanced lap, further pediatric data on omentectomy vs omentopexy

KEY QUESTION 6

Should advanced laparoscopic insertion techniques or ultrasound-guided percutaneous techniques be used for adult patients needing renal replacement therapy?	
POPULATION:	Adult patients needing renal replacement therapy
INTERVENTION:	Advanced laparoscopic insertion
COMPARISON:	Ultrasound-guided percutaneous insertion
MAIN OUTCOMES:	Bleeding; Bowel Injury; Catheter Dysfunction - Early (<3mon); Catheter Dysfunction - Late (>3mon); Hernia Occurence; Exit Site Infection; Leakage; Mortality; Peritonitis;
SETTING:	
PERSPECTIVE:	Patient centered
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote:** Yes (100%)	

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies	**Vote:** Small (100%)	

○ Don't know		

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Perc	Risk difference with Adv Lap
Bleeding	282 (2 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.32** (0.07 to 1.36)	Study population	
				50 per 1,000	**33 fewer per 1,000** (46 fewer to 17 more)
Bowel Injury	495 (2 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.31** (0.04 to 2.63)	Study population	
				12 per 1,000	**8 fewer per 1,000** (12 fewer to 19 more)
Peritonitis	325 (3 observational studies)	⨁◯◯◯ Very low[a,b,c]	**OR 0.95** (0.47 to 1.93)	Study population	
				167 per 1,000	**7 fewer per 1,000** (81 fewer to 112 more)

a. Included studies did not employ statistical matching, thus introducing some bias into the comparability of the cohorts.
b. Very small event rate which creates some fragility within the outcome.
c. The range of effects spans several clinically important thresholds.

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know	**Vote:** Small (100%)	Early catheter dysfunction and mortality were considered inconclusive by panel. Mortality included long term mortality and was not short-term, not thought to be related to technique.

Outcomes	№ of participants (studies) Follow-up	Certainty of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects* (95% CI)	
				Risk with Perc	Risk difference with Adv Lap
				Study population	

Catheter Dysfunction - Early (<3mon)	43 (1 observational study)	⨁◯◯◯ Very low[a,b,c]	**OR 1.67** (0.25 to 11.13)	91 per 1,000	**52 more per 1,000** (67 fewer to 436 more)
Catheter Dysfunction - Late (>3mon)	537 (4 observational studies)	⨁◯◯◯ Very low[c,d]	**OR 1.46** (0.83 to 2.57)	Study population	
				112 per 1,000	**44 more per 1,000** (17 fewer to 133 more)
Hernia Occurence	325 (3 observational studies)	⨁◯◯◯ Very low[b,c,d]	**OR 1.19** (0.40 to 3.55)	Study population	
				49 per 1,000	**9 more per 1,000** (29 fewer to 106 more)
Exit Site Infection	325 (3 observational studies)	⨁◯◯◯ Very low[b,c,d]	**OR 1.15** (0.39 to 3.40)	Study population	
				59 per 1,000	**8 more per 1,000** (35 fewer to 116 more)
Leakage	537 (4 observational studies)	⨁◯◯◯ Very low[b,c,d]	**OR 1.71** (0.40 to 7.31)	Study population	
				29 per 1,000	**20 more per 1,000** (17 fewer to 152 more)
Mortality	213 (1 observational study)	⨁◯◯◯ Very low[b,c,d]	**OR 1.57** (0.68 to 3.66)	Study population	
				102 per 1,000	**49 more per 1,000** (30 fewer to 192 more)

a. There was a considerable amount of missing information within this study, thus introducing some bias.
b. Very small event rate which creates some fragility within the outcome.
c. The range of effects spans several clinically important thresholds.
d. Included studies did not employ statistical matching, thus introducing some bias into the comparability of the cohorts.

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies	**Vote:** Very low (100%)	

Outcomes	Importance	Certainty of the evidence (GRADE)
Bleeding	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Bowel Injury	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Catheter Dysfunction - Early (<3mon)	CRITICAL	⨁◯◯◯ Very low[b,c,d]
Catheter Dysfunction - Late (>3mon)	CRITICAL	⨁◯◯◯ Very low[a,c]
Hernia Occurence	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Exit Site Infection	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Leakage	IMPORTANT	⨁◯◯◯ Very low[a,b,c]
Mortality	CRITICAL	⨁◯◯◯ Very low[a,b,c]
Peritonitis	CRITICAL	⨁◯◯◯ Very low[a,b,c]

a. Included studies did not employ statistical matching, thus introducing some bias into the comparability of the cohorts.
b. Very small event rate which creates some fragility within the outcome.
c. The range of effects spans several clinically important thresholds.
d. There was a considerable amount of missing information within this study, thus introducing some bias.

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ○ Possibly important uncertainty or variability ● Probably no important uncertainty or variability ○ No important uncertainty or variability	**Vote:** Probably no important uncertainty or variability (100%)	

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ○ Probably favors the comparison ● Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know	**Vote:** Does not favor either the intervention or the comparison (100%)	

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know	**Vote:** Yes (100%)	

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know	**Vote:** Probably Yes (100%)	

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	Possibly important uncertainty or variability	**Probably no important uncertainty or variability**	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	Probably favors the comparison	**Does not favor either the intervention or the comparison**	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	Probably yes	**Yes**		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	**Conditional recommendation for either the intervention or the comparison**	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	●	○	○

CONCLUSIONS

Recommendation

Justification

Subgroup considerations

- In pts with prior abdominal operations, the percutaneous approach could have a higher complication rate
- obesity

Implementation considerations

Monitoring and evaluation

Research priorities

IR vs nephrologists vs surgeons
Subgroup analysis – virgin abd vs. prior abd surgery
Obesity

KEY QUESTION 7

In adult patients with PD catheter malfunction, should nonoperative or operative salvage be attempted?	
POPULATION:	Adults needing renal replacement therapy
INTERVENTION:	Nonoperative salvage
COMPARISON:	Operative salvage
MAIN OUTCOMES:	
SETTING:	
PERSPECTIVE:	
BACKGROUND:	
CONFLICT OF INTERESTS:	

ASSESSMENT

Problem

Is the problem a priority?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ○ Probably yes ● Yes ○ Varies ○ Don't know		

Desirable Effects

How substantial are the desirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Trivial ● Small ○ Moderate ○ Large ○ Varies	There were no comparative studies looking at salvage of PD catheter. Below are outcomes which had single arm data for both intervention and comparator. **Single Arm Data (I2 presented if >40%):**	Small 100%

○ Don't know	**Bleeding:** Nonop Salvage (1 study) 0.9% (0.1%-13.4%) Operative Salvage (5 studies) 3.3% (1.3%-8.5%) **Exit Site Infection:** Nonop Salvage (1 study) 0.9% (0.1%-13.4%) Operative Salvage (5 studies) 6.6% (1.6%-23.6%; I2 74.1%) **Peritonitis:** Nonop Salvage (2 studies) 1.1% (0.2%-5.2%) Operative Salvage (5 studies) 7.1% (3.8%-12.9%)	

Undesirable Effects

How substantial are the undesirable anticipated effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Large ○ Moderate ● Small ○ Trivial ○ Varies ○ Don't know	**<u>Single Arm Data (I2 presented if >40%):</u>** **Early Catheter Dysfunction:** Nonop Salvage (3 studies) 39.1% (26.4%-53.5%; I2 61.7%) Operative Salvage (10 studies) 17.7% (8.4%-33.8%; I2 67.6%) **Late Catheter Dysfunction:** Nonop Salvage (1 study) 31.6% (14.9%-54.8%) Operative Salvage (8 studies) 29.3% (14.8%-49.8%; I2 71.9%)	Small 100%

Certainty of evidence

What is the overall certainty of the evidence of effects?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
● Very low ○ Low ○ Moderate ○ High ○ No included studies		very low 100%

Values

Is there important uncertainty about or variability in how much people value the main outcomes?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Important uncertainty or variability ● Possibly important uncertainty or variability ○ Probably no important uncertainty or variability ○ No important uncertainty or variability		Possibly important uncertainly or variability 100%

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ Favors the comparison ● Probably favors the comparison ○ Does not favor either the intervention or the comparison ○ Probably favors the intervention ○ Favors the intervention ○ Varies ○ Don't know		Although magnitude of desirable and undesirable effects both small, panel felt outcome of catheter dysfunction more important to pts and thus balance favors operative salvage (comparison). Probably favors the comparison 100%

Acceptability

Is the intervention acceptable to key stakeholders?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS
○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know		Probably yes 100%

Feasibility

Is the intervention feasible to implement?

JUDGEMENT	RESEARCH EVIDENCE	ADDITIONAL CONSIDERATIONS

○ No ○ Probably no ● Probably yes ○ Yes ○ Varies ○ Don't know		Conceivable that a hospital may not have TPA or IR skillset available. Probably yes 100%

SUMMARY OF JUDGEMENTS

	JUDGEMENT						
PROBLEM	No	Probably no	Probably yes	**Yes**		Varies	Don't know
DESIRABLE EFFECTS	Trivial	**Small**	Moderate	Large		Varies	Don't know
UNDESIRABLE EFFECTS	Large	Moderate	**Small**	Trivial		Varies	Don't know
CERTAINTY OF EVIDENCE	**Very low**	Low	Moderate	High			No included studies
VALUES	Important uncertainty or variability	**Possibly important uncertainty or variability**	Probably no important uncertainty or variability	No important uncertainty or variability			
BALANCE OF EFFECTS	Favors the comparison	**Probably favors the comparison**	Does not favor either the intervention or the comparison	Probably favors the intervention	Favors the intervention	Varies	Don't know
ACCEPTABILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know
FEASIBILITY	No	Probably no	**Probably yes**	Yes		Varies	Don't know

TYPE OF RECOMMENDATION

Strong recommendation against the intervention	Conditional recommendation against the intervention	**Conditional recommendation for either the intervention or the comparison**	Conditional recommendation for the intervention	Strong recommendation for the intervention
○	○	●	○	○

CONCLUSIONS

Recommendation

Conditional recommendation for either the intervention or the comparison

Justification

The panel recommends a trial of nonoperative salvage prior to operative intervention as long as it is felt to be safe. However, operative salvage may be more successful.

Subgroup considerations

If hemodialysis not an option, may want to proceed with operative intervention as it seems more likely to succeed. If IR unavailable or if TPA contraindicated may need to proceed with operative salvage.

Implementation considerations

Monitoring and evaluation

Research priorities

Comparative studies. Prospective large series data. Multicenter prospective data. A homogenous population where only one intervention is being investigated.